

# **BioPolis**

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

### **Final Report**

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## **Foreword**

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## Executive Summary

### Objective

Modern biotechnology is one of today's key enabling technologies. It has become the driving force of dramatic changes in innovation processes in many sectors. However, the development and implementation of biotechnology is rather diverse across countries. Although part of the explanation might come from historical, geographical, economic or demographic factors, government policy measures are an important key for understanding why biotechnology shows such large differences in growth patterns between countries. Policy makers have developed a variety of different policies and policy instruments to foster biotechnology innovation processes. The first aim of BioPolis is to provide an up-to-date and detailed overview of these national and regional biotechnology policies and policy instruments for the period 2002-2005 in all EU Member States, four Accession Countries, and Norway, Iceland and Switzerland. The second aim is to assess the effectiveness of biotechnology policies by exploring the relationship between national policy approaches towards biotechnology and the performance of the respective national biotechnology innovation systems.

### Methodology

BioPolis combines qualitative and quantitative methods in order to provide the in-depth overviews of national policy instruments that foster biotechnological growth and performance in science and commercialisation of biotechnology. A guidebook was developed with a common methodology for the national case studies that included the definition of biotechnology, an overview of relevant actors in the national biotechnology innovation systems, a data collection sheet for policy instruments, data sources and suggestions for data validation. All data on policy instruments were fed into a common database to support analysis. This Final Report with the results of the cross country analysis builds on the findings of 32 country studies which form the core part of the BioPolis project.

The overall presentation and cross country analysis of policies, performance, policy dynamics and policy effectiveness in this Final Report is presented separately for the 15 Old Member States plus Iceland, Norway and Switzerland (referred to as EU15+3) and for the 10 Member States that joined the European Union in May 2004 (Hungary, Poland, Czech Republic, Slovak Republic, Slovenia, Estonia, Latvia, Lithuania, Malta and Cyprus), the two which joined in January 2007 (Bulgaria and Romania) and a further two which are in accession negotiations (Croatia and Turkey), referred to as: NMS and AC. This is because previous studies provide data on biotech policy profiles, policy goals and policy instruments for the EU15+3 for the period 1994-1998 (Inventory) and 2001 (Epohite). On the basis of the results of these studies, an analysis of the dynamics in biotech policy making in the period 1994-2005 for EU15+3 can be made. Also conclusions on the effectiveness of past policies (Inventory and Epohite) can be evaluated for the EU15+3 on the basis of national performance data (as presented in BioPolis). Most NMS and AC have only recently started formulating their biotechnol-

ogy policies and implementing specific instruments. Due to the specific (historical) situation of NMS and AC, only a small number of indicators could be used for measuring the outcome of their national biotechnology innovation systems. Although data collection was rather difficult and is not complete for some of the NMS and AC, BioPolis provides a first overview of the biotechnological innovation systems and the biotechnology policies and performance in NMA and AC.

## **Key findings and policy recommendations**

### **Methodology**

A number of methodological issues are relevant to the success of studies such as BioPolis; the most important is the availability of comparable data. We are confident that the overview of biotech-specific and generic instruments and the non-policy-directed funding is rather complete for most of the EU15+3. Moreover, in these countries the comparability of data is rather high, as data collection tends to comply, for instance, with OECD guidelines. In addition, consultancy firms have collected data on high tech biotechnology firms for many years. However, the availability and comparability of such data is rather poor in most of the New Member States and Accession Countries. One reason might be that some countries lack a tradition for collecting and presenting data on instruments and funds for specific technology fields. This implies that the data presented in some National Reports and this Final Report are underestimates of the biotechnology funding in those countries and thus also in Europe. In some cases rough estimates had to be used for some instruments.

Furthermore, the performance analysis of NMS and AC, particularly publications data, have to be treated with great caution as many publications are still in national languages and thus not covered by the database used (SCI). Performance in publications in NMS and AC reflects the uptake of English and integration into the international scientific community. For NMS and AC the number of dedicated firms is not yet collected in a comparable and systematic way. *It is recommended to encourage NMS and AC to build up their capabilities to gather data, conforming to OECD standards where relevant, for S&T policies and budgets.*

Comparative data about the biotech activities of diversified biotech companies (number of firms, employees active in biotech; size of their biotech activities) are not available for any of the 32 countries.

### **Configuration of national policy making systems**

Analysis of the configuration of national policy making systems shows that countries with convergent innovation systems – with high interactions amongst a large diversity of actors and concentrated decision making processes with *ex ante* coordination - appear to perform better than divergent ones. All weak performers have a fragmented system with low interactions between small numbers of actors, except for Portugal where a large number of actors are involved. Increasing coordination between different policies and between the responsible actors seems to contribute to increased policy effectiveness. In most NMS and AC many shortcomings with the policy-making process are reported, es-

pecially the low level of coordination of government policy, the small range of actors involved in policy formulation and the creation of policy instruments to implement research priorities.

One of the strongest trends since 1994 in the national biotechnology policy making systems in EU15+3 countries is the rise in regional government participation in biotechnology policy-making. In the period 1994-98 there was significant regional policy-making for biotechnology in Member States where the regions have responsibility for supporting university research and economic development (Germany, Belgium and Spain) and, to a lesser extent, in some regions of the UK. By 2002-2005 regions in these countries and in Austria, France and Italy were playing a very active role in biotech policy-making; they tend to focus their efforts on research commercialisation and support to SMEs.

The focus of first and second generation innovation policies was on the research and education system, the business system, framework conditions, infrastructure and intermediaries. However, the systems approach of the second generation seems to have neglected the role of the government and its constituent part (i.e the policy system). *As our results show that policy coordination 'pays', it is highly recommended that national governments close the "coordination gap"; not only between national departments, but also between national and regional governments and international institutions. This involves co-ordination of simultaneous policy actions addressing the core set of innovation policies such as science, technology and education, as well as a re-direction of policy actions that pursue other primary objectives such as public health and regional development.*

Particularly due to the complex nature of biotechnology innovation processes, a broad and up-to-date information base and the inclusion of different perspectives are important prerequisites for the design of successful policies. This can be achieved by enabling meaningful participation by non-government biotechnology actors – particularly representatives of the scientific community, industry, but also consumer and patient groups – in the policy process. Apart from the composition of the biotechnology policy arena, managing the processes within such a policy network warrants special attention. *A higher intensity of mutual information exchanges, not only between the responsible ministries and agencies but also within a broader set of non-government actors involved in biotechnology, may help to mitigate potentially damaging conflicts within the policy network, contribute to the development of shared understanding, and eventually foster policy-learning.*

## **Performance**

With respect to the overall performance in biotechnology the analysis shows that the EU15+3 countries can be grouped into three clusters: Cluster 1 with the best performing countries includes Switzerland, Denmark, Sweden and Finland. Cluster 2 performs at a roughly similar level to the European median and includes Austria, Belgium, the Netherlands, Ireland, Norway, Germany, France and the United Kingdom. Cluster 3 - Italy, Greece, Spain, Portugal and Luxembourg - performs well below the European median. Iceland is a special case: due to limited data availability it is not included in the cluster analysis.

The analysis of scientific performance and commercialisation performance of the individual countries provides clear evidence of a positive correlation between the two. Therefore: *nations wishing to sustain or improve their commercial performance in biotechnology will not be successful if they focus their supporting activities only on functions of the innovation system which are directly related to commercialisation. Rather, it is important to take a holistic approach towards the system, taking care of both the scientific and the commercialisation sub-systems.*

Our systematic performance analysis considers the European Union as a whole, the individual countries and the United States. A main conclusion that can be drawn by **comparing Europe with the United States** is that with respect to most performance indicators, the United States performs at a similar level to the best European countries. However, the position of Europe as a whole seems less favourable when compared with the United States. Considering the great diversity in performance of European countries and the situation in the United States where biotechnology excellence is concentrated in few regions (such as the Boston area, North Carolina, Southern and Northern California), it seems questionable to compare Europe as a whole with the United States as a whole. *Such regional units in the United States might be better suited for comparative analysis of performance in biotechnology with individual European countries than the United States as a whole.*

### **Policy profiles and policy effectiveness**

Biotechnology has received increased priority in national innovation policies in EU15+3: the annual funds spent on biotechnology between the periods 1994-1998 and 2002-2005 almost doubled. However, the relative contribution of funds to biotech specific and generic instruments in total funds has scarcely changed. Since the period 1994-1998 a large number of new biotech-specific and generic instruments were introduced, especially instruments to stimulate technology transfer and commercialisation. This might reflect a trend in biotechnology policy making: a shift of focus from science based to commercialisation based biotechnology policies. This trend to promote commercialisation was already visible in 2001, especially in countries that had a rather complete profile in terms of coverage of all policy goals by a combination of biotech specific and generic instruments. In these countries the policy profile has scarcely changed during the last ten years. The trend towards commercialisation is now also visible in countries that formerly had a more incomplete profile.

The analysis of the effectiveness of **specific science base policies** seems to indicate that having only generic research stimulating instruments in place is less effective; biotech specific instruments seem to be more beneficial. Most highly performing countries gave equal emphasis to basic and applied research or had some stronger focus on supporting basic research. Where support for the international mobility of researchers has been implemented, it seems to be beneficial to output. This is in particularly relevant for smaller countries that have limitations in the diversity of their domestic knowledge base. Support of the development of human resources specialised in biotechnology and regulations fostering research activities seem to make no differences in terms of performance.

The analysis of policy approaches aimed at the **commercial exploitation of biotechnology** indicates that all highly performing countries had generic and biotech-specific instruments in place. All the countries performing below the European average had generic instruments but a number of these countries did not use biotech specific policy instruments. No clear conclusions could be drawn on the effectiveness of policy support measures for biotechnology research in industry or on the effect of the regulatory framework. These observations support the notion that generic exploitation approaches only are not sufficient.

Overall analysis of policy effectiveness shows that policy profiles that have a balanced mix of generic and biotech-specific instruments and that support the science base and commercialisation activities are more successful (i.e. show higher performance levels) than countries whose policy profiles give low importance to some of these policies. In other words: **public policies matter**.

*It is recommended that countries implement a well balanced mix of instruments that target the creation and sustenance of a competitive biotechnology knowledge base and commercialisation. The importance of supporting commercialisation should not lead to policy profiles with an overly heavy accent on these policy goals. In countries with weak scientific performance and low research expenditure special emphasis should be given to biotech-specific policies because these are essential to building up scientific capabilities.*

### **Policies and performance of NMS and AC**

Many of the NMS and AC are undergoing significant restructuring and lack adequate public resources to invest in research in general, and in biotechnology in particular. BioPolis has found that they contributed only around 2% of total expenditure on biotechnology research of the 32 European countries covered. This is an underestimate, because complete information on expenditure for some countries is lacking. Nevertheless, even if the complete budget data had been gathered, their share would still remain very low.

In addition to low investment, BioPolis identified **shortcomings in the funding systems** in many of the NMS and AC. Previous research suggests that a system where funds are allocated by research councils through a competitive, peer-reviewed process allows *ex ante* coordination, before the implementation of strategic decisions. By contrast, the funding of research through the allocation of block grants gives autonomy to organisations over the research agenda, and coordination can only be carried out *ex post*. Moreover, competitive research funding is not only flexible; it also appears to be a more effective method than direct control of funds by research institutions to achieve a strong international orientation and higher scientific performance. In many NMS and AC a high proportion of research funding is also allocated as block grants to universities and/or institutes. *Research performance of NMS and AC would benefit by taking steps to move away from a research system principally based on the allocation of block grants. The quality and relevance of research is likely to be enhanced by greater use of competitive, peer-reviewed research grants. However, block grants may be allocated to public research centres dedicated to a specific area of research, e.g. molecular biology, with*

*continued funding being dependent on the outcome of regular evaluations of performance (as is the case in some Old Member States).*

### **Specialisation pattern**

We observed more or less the same national specialisation patterns in biotechnology throughout Europe. The overall specialisation pattern of EU15+3 did not change very much since 1994: red biotech (health) is by far still the most important, followed by green biotech (agrofood: about one third of the health budget) and finally white biotech (industrial and environmental biotech). However, the position of white biotech improved as its relative contribution rose from 11% to 16%, at the expense of red and green biotech. The high focus on health biotech was even more strongly visible in the publication output. In the period 1994-1996, the NMS and AC had a slightly different pattern of specialisation, with fewer publications in the health area and more in plant, animal and industrial biotechnology than the EU15+3. However, publication patterns for 2002-2004 show that NMS and AC have been converging toward the EU15+3 pattern and not retaining their early pattern of specialisation.

The observed lack of variety in focus on specific biotechnology application areas among European countries raises the question of the current status of a **European research area** in this field. Obviously, such a construct seems far from being realised at present. *Considering the differing industrial orientations of European countries and, accordingly, the differing opportunities for the industrial adoption of biotechnology, it does not seem to be advisable to strive for similar specialisation goals in biotechnology. This would lead to a uniform European research area that did not take advantage of national strengths. A system combining various national specialisations based on different national industrial strengths would be more competitive.*

BioPolis provides the first in-depth overview of the biotechnology policy making systems and policies of the NMS and AC. These countries are mainly latecomers to the development and exploitation of biotechnology. They are correct to develop capability in this significant technology which has a rapidly expanding knowledge base. Without such capability they will lack the competence to absorb and utilise the knowledge which is being created in the rest of the world. For NMS and AC there is a danger that in attempting to secure benefit from their investments in public biotechnology research these countries will focus on exploiting the potentially high value-added, pharmaceutical applications of biotechnology. If they follow this strategy, however, they are unlikely to succeed, as the competition is too strong. In addition - and this applies also to Old Member States - there is need for capabilities in myriad new platform technologies. Building up an adequate knowledge base in even one of these areas requires very large research teams, and it would be unwise for these countries to concentrate limited resources for biotechnology on a few research areas only. *NMS and AC are more likely to succeed if they support biotechnology research that is relevant to strong economic sectors within their countries.* There are some older Member States that provide examples of how to do this. They are building up competence in niche areas of biotechnology where they have the potential to achieve competitive advantage.

## 1. Introduction

Modern biotechnology is one of the key enabling technologies of today. It has become the driving force for dramatic changes in innovation processes in many sectors. However, the development and implementation of biotechnology is rather diverse across countries and also within countries (Enzing et al 1999; Reiss et al. 2003, 2005; Cooke 2001). Although part of the explanation might come from historic, geographic, economic or demographic factors, government policy measures are an important key for understanding why biotechnology shows such large differences in growth patterns between countries (see also Arantes-Oliviera 2007).

The role of government in innovation policy has changed considerably over the last decades. Traditionally, the emphasis of the first generation of governments' innovation policies was on fostering critical directions in science and technology (especially basic – i.e. generally applicable – research) and enhancing the flow of knowledge along the innovation chain. Based on the linear model of innovation, the funding of research “at a certain distance from the market” was designed to compensate for so-called market failures.

In the 1990s, the non-linear and more interactive nature of innovation processes was recognized. This led to a systems approach to innovation, defining innovation system as a system of institutional actors and factors that together play a major role in influencing innovative performance (Nelson and Rosenberg 1993). However, innovation systems are not perfect; systemic failures may block the functioning of the innovation process. These failures - such as inadequate framework conditions and infrastructure provision, or network and capability failures - provide an extra rationale for government intervention in ensuring that the innovation system performs well (second generation policies). This merely applies to generic policies. Bozemann and Dietz (2001) argue that the policy role in selecting and fostering specific technological fields (such as biotechnology) is based on arguments beyond strict economic rationales and has a stronger basis in political motives.

However, as there is no single theory of national innovation systems, making a complete understanding of these systems practically impossible, policy makers have no clear guidance on what to do. Accordingly, simple rule-based policy, as is available for static market failure, cannot be formulated (Haukness and Norgren 1999). In addition, historical analysis shows that priority setting is inherently context dependent, changes over time in its rationales and goals and is different between national innovation systems (Gassler et al. 2004). Given these circumstances, there is nothing left for policy makers but continuously identifying and rectifying structural imperfections. Therefore a key role for second generation policy making is “bottleneck analyses” (Arnold 2004). On the basis of overall intelligence - that is developed continuously in a national system of innovation - governments can decide where and how to intervene. In pragmatic terms, this makes it possible to make iterative improvements and put policy learning into practice.

Although policy structures exhibit inertia, they also have dynamic aspects. These dynamic aspects result from improved understanding of the agents, interactions and patterns that are the objects of policy (Mytelka and Smith 2002). So, learning processes within policy systems deal with the implementation of lessons from past performance into the development of future policies.

Within the domain of biotechnology policy making, the results of the BioPolis project can be an important input into such policy learning processes. The general aims of the BioPolis project are twofold. Firstly, it wants to provide an up-to-date and detailed overview of national and regional biotechnology policies in all EU Member States, four accession countries and Norway, Iceland and Switzerland, in the period 2002-2005. The second aim is to assess the effectiveness of biotechnology policies by exploring the relationship between national policy approaches towards biotechnology and the performance of the respective national biotechnology innovation systems.

BioPolis provides national policy makers with an in-depth overview of the national biotechnology policy-making systems and the policies to support biotechnology that were implemented between 2002 and 2005 in 32 European countries. Although for some of the New Member States data collection was rather difficult and is not complete, BioPolis provides a first overview of the biotechnological innovation systems and biotechnology policies and performance in these countries. Conclusions on the effectiveness of past policies in European Member States as presented in the Inventory report (Enzing et al. 1999), Epohite report (Reiss et al. 2003) and Polybench report (Reiss et al. 2005) are evaluated on the basis of national performance data (as presented in BioPolis)<sup>1</sup>. BioPolis presents recommendations that can be a valuable input for new policy making processes.

BioPolis combines qualitative and quantitative methods in order to provide an in-depth overview of national policy instruments that foster biotechnological growth, to quantify national performance in biotechnology and to draw overall conclusions based on policy dynamics and policy effectiveness in 32 countries since 1994. BioPolis tries to take into account the fact that factors other than policy also influence the innovation process and thus affect performance and that there is a time lag between the implementation of a policy and its outcome. The next chapter of this report presents the methodological approach of BioPolis.

The overall presentation and cross country analysis of policies, performance, dynamics and effectiveness is presented separately for the 15 Old Member States plus Iceland, Norway and Switzerland (referred to as EU15+3) and for the 10 Member States that joined the European Union in May 2004

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<sup>1</sup> The BIOPOLIS takes advantage of previous research activities in the field of biotechnology innovation policy studies funded by the European Commission: the Inventory project (Enzing et al. 1999), the Epohite project (Reiss et al. 2003) and the Polybench project (Reiss et al. 2005). The Inventory project presented a detailed overview of biotechnology policies (instruments and funding) in EU15 (minus Luxembourg), Iceland, Norway and Switzerland. The Inventory presented input data. The Epohite project and the Polybench project both focus on developing and implementing indicators to assess the output of national biotechnology innovation systems in Europe. In the Epohite project information on policy approaches and national performance in biotechnology of 14 European countries for the period 1994 - 2001 has been gathered. In the Polybench project a comprehensive set of indicators is composed that allows benchmarking of biotechnology policies by policy makers throughout Europe.

(Hungary, Poland, Czech Republic, Slovak Republic, Slovenia, Estonia, Latvia, Lithuania, Malta and Cyprus), the two which joined in January 2007 (Bulgaria and Romania) and a further two which are in accession negotiations (Croatia and Turkey), referred to as: NMS and AC.

This is not only for practical reasons but mainly because of the following:

- The Inventory and Epohite reports provide data for the period 1994-1998 and 2001 on policy profiles, goals and instruments for the EU15+3; this allows a comparison with the situation in 2002-2005 for EU15+3.
- Most NMS and AC have only recently started formulating their biotechnology policies and implementing specific instruments.
- Given the poor data availability for NMS and AC, the indicators that could be used to measure the outcomes of policies in EU15+3 versus those in NMS and AC showed considerable differences. Due to the specific (historical) situation of NMS and AC, only a small number of indicators could be used for measuring the outcomes of their national biotechnology innovation systems.

Hence, chapters 3 to 7 focus on EU15+3, whereas chapter 8 deals exclusively with the 10 New Member States and the four Accession Countries. Chapter 3 provides an overview of the basic institutional configurations in EU15+3, particularly those dealing with processes of biotechnology policy-making and the implementation of public biotechnology policies. Chapter 4 contains overall data on the funding of biotechnology during the period 2002-2005. Chapter 5 presents the performance analysis of the EU15+3, based on quantitative indicators. Changes to biotechnology policy-making in the EU15+3 since the period 1994-98 are reviewed and presented in Chapter 6. Chapter 7 summarises the main conclusions on policy effectiveness in the EU15+3. Chapter 8 presents information about biotechnology policy instruments and performance of the NMS and AC.

The results of previous studies on the effectiveness of policies (Epohite, Polybench) may have affected the learning processes of policy makers in Europe in up-dating and renewing biotechnology policies and policy instruments. As most of the New Member States are still in an early stage of biotechnology policy development, BioPolis considers these countries as an important group to which the conclusions and recommendations (Chapter 9) are addressed. However, the conclusions and recommendations may also have relevance to countries which are failing to achieve the desired outcomes from their policy interventions.

Each of the chapters of this final report builds on inputs from the project participants that collaborated in the BioPolis project team. TNO was responsible for drafting chapters 1, 2, 4 and 9. Fraunhofer ISI was responsible for drafting chapters 3 and 5 and co-authored the drafting of Chapter 7 together with TNO. SPRU was responsible for chapter 8 and co-authored the drafting of Chapter 6 together with TNO. This Final Report, with the results of the cross country analysis, builds on the findings of 32 country studies which form the core part of the BioPolis project and have been conducted under the

responsibility of the members of the three teams. All national reports are available on a CD-ROM which is provided as a supplement to this Final Report.

## 2. Methodology

This chapter introduces the methodology that was used in BioPolis. It addresses the main methodological issues in preparing an inventory of policies and policy instruments, in measuring the national performance in biotechnology through a number of indicators and in the analysis of policy dynamics and policy effectiveness.

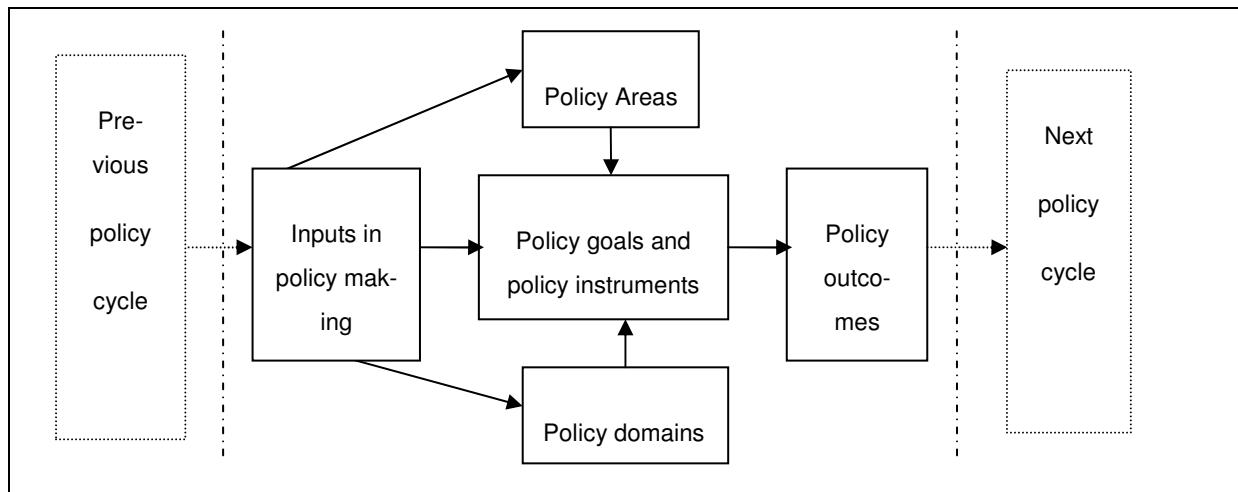
The general approach of BioPolis is introduced in section 2.1. Section 2.2 presents the definition of biotechnology that is used in BioPolis. Section 2.3 covers methodological issues, the categorisation of policy instruments and finally presents the indicators used to measure national performance in biotechnology.

### 2.1 General approach and research tools

BioPolis takes a systemic and dynamic view on the biotechnological innovation process. This systemic view includes the interactions between the relevant actors in the national biotechnology innovation system and other factors affecting biotechnological innovation processes (see Chapter 3 for a more detailed overview of this system).

Figure 2.1 shows the general view on policy formation from a dynamic and systemic perspective which served as the basis for the general methodological approach used in BioPolis.

Figure 2.1 General view on policy formation from a dynamic and systemic perspective: chain of policy cycles



Source: BioPolis Research

Policy makers may use several types of inputs, including information on policy outcomes, in order to up-date and renew their science & technology and innovation policies and policy instruments. In that respect the situation sketched in Figure 2.1, must be considered as belonging to a chain of groups of events (policy cycles) in which policy makers evaluate past policies and performance and use the

outcome of this evaluation when starting a new cycle of developing, implementing and evaluating policies, and so on.

From this systems perspective on the innovation process, four policy areas for potential policy intervention in biotechnology innovation systems have been defined, covering nine policy goals and their instruments.

The four policy areas focus on (based on Reiss et al. 2005):

- the generation and maintenance of a knowledge base for biotechnology and the availability of human resources;
- the transfer of biotechnological knowledge from the sites of its generation to possible loci of application;
- the full integration of biotechnology into economic and public sectors via the successful introduction of biotechnology-based products and services into markets and public services (including public health, food safety, clean environment);
- the industrial development of the biotechnology sector including small and medium sized firms and large firms.

These four policy areas involve key processes of the innovation system for which nine specific policy goals can be formulated (see table 2.1). Each of the goals can be achieved by the implementation of one or more policy instruments; examples are presented in column 3 of Table 2.1. By using these instruments, policy makers try to influence the biotechnology activities of specific actor groups in the biotechnology innovation system.

Table 2.1 Policy areas, policy goals and policy instruments

Policy areas	Policy goals	Examples of policy instruments
1. Creation of knowledge base and human resources	1. To promote a high level of biotechnology basic research	R&D programmes that fund basic research in biotechnology-related fields
	2. To promote a high level of industry-oriented (and applied) research	R&D programs that fund applied research in biotechnology
	3. To support knowledge flow and collaboration among scientific disciplines	Support for centres of excellence in interdisciplinary research Support for mobility of researchers
	4. To assure the availability of human resources	Measures to improve (post) graduate biotechnology training
2. Knowledge exchange and application	5. To facilitate transfer of knowledge from academia to industry and its application for industrial purposes	Grants for industrial research involving public sector researchers Create technology transfer offices and science and technology parks Support for protection of intellectual property at universities
	6. Stimulate the adoption of biotechnol-	Awareness campaigns for biotechnol-

	ogy for new industrial applications	ogy
	7. To assist firm creation	Creation of incubators Financial and other support for start-ups
3. Market	8. To inform the public and facilitate a dialogue with the public and other stakeholders	Support of discourse activities, e.g. citizen panels and consensus conferences
4. Industrial development	9. To encourage business investment in R&D	Grants for industrial research (Fiscal) incentives for business investment in R&D

Sources: Reiss et al. 2005, BioPolis Research

The nine policy goals can be assigned to seven policy domains: research policies, education policies, exploitation policies; industrial development policies, fiscal policies, regulation and demand-oriented policies. These domains basically cover the whole range of possible policy portfolios within the policy-making system. Policy domains can be covered by one or more policy goals and their instruments.

## 2.2 Definition of biotechnology

In general BioPolis tries to comply with the definition used by the OECD, as this will facilitate comparability of data with published statistics. The OECD definition consists of two parts. The first part provides a conceptual definition of biotechnology. The second part provides a list of technologies that are considered as biotechnologies. BioPolis has added a third part which provides a list of application areas.

### ***Part 1: Single definition of biotechnology***

The version of the OECD so-called 'single definition' that was used for BioPolis is presented in the Biotechnology Statistics Framework of 16 December 2004<sup>2</sup> (OECD 2004).

This conceptual definition of biotechnology of the OECD is: "*The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.*"

### ***Part 2: List-based definition of biotechnology***

The list-based definition of biotechnology is a list of technologies used in biotechnological research and production. This list (see Table in Annex 2) is composed on the basis of three sources: the list-based definition of the OECD (16 December 2004), the list of biotechnologies of the US Department of Commerce (August 2002) and the list provided in the EBIS-project (December 2001). In the OECD

<sup>2</sup> As the BioPolis project started 1 December 2004, BioPolis used the OECD definitions of biotechnology that were published in the document of 16 December 2004. The definitions have been included in the BioPolis Guidebook that presented a common methodology for the BioPolis country studies. Since December 2004 the OECD has published new documents holding more or less the same definitions.

Biotechnology Statistics Framework (16 December 2004), a glossary of biotechnologies is included in the annex, developed by the German and Canadian delegates. Some of these new terms are also included in the list.

### ***Part 3: Application areas***

BioPolis uses the following list of biotechnology application areas:

1. Plant biotechnology
2. Animal biotechnology
3. Environmental biotechnology
4. Health biotechnology (human and animal health; including drugs, diagnostics, vaccines, cell therapy, embryonic stem cells, tissue engineering and other therapies)
5. Food biotechnology
6. Industrial biotechnology (production of intermediates for number of end industries, including chemical biotechnology)
7. Basic biotechnologies (in case basic R&D and/or technology are subject of a programme that can not already be awarded to an application area)
8. Non-technical areas of biotechnology.

This list is based on the list of biotechnology areas used in the Inventory. However, as two categories in the Inventory list did not discriminate between food and industrial biotechnology (although similar techniques might be used) the two Inventory categories B.4 and B.5<sup>3</sup> were replaced by the categories 5 (food biotechnology, including enzymes, yeast) and 6 (industrial biotechnology) in BioPolis. This has been taken into account in the comparison of the coverage and funding of areas between the Inventory and BioPolis periods (Chapter 6).

Biotechnology and life sciences are interlinked and often also mentioned together in policy papers (for instance in the European Strategy on Life Sciences and Biotechnology of the European Commission published in 2002). Biotechnology is an important enabling technology in life sciences research; a number of biotechnologies also have been developed in the laboratory for research purposes. However, biotechnologies have also been developed and are used in other contexts: development, production, downstream processing, etc.

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<sup>3</sup> B.4 Industrial biotechnology: food/feed, paper, textile, and pharmaceutical and chemical production, including enzymatic processes, development of bio-processing techniques and downstream processing

B.5 Industrial biotechnology: cell factory, including all biotechnology research focused on all sorts of (food and non-food) applications, including plant and animal cell biology, bacteria as cell factory, genetic engineering and production of enzymes, yeast and other micro-organisms

In BioPolis biotechnology includes all activities related to biotechnology research, the development of biotechnology techniques and their application. It excludes the use of biotechnology tools in other research areas, such as biological, medical or chemical research.

## 2.3 BioPolis research tools

The BioPolis inventory and analysis of policy dynamics and policy effectiveness combines quantitative and qualitative research tools:

- Quantitative categorization of national and regional policies, policy goals and instruments during the period 2002-2005 in all Member States, Iceland, Norway, Switzerland, and four Accession Countries on the basis of desk research and interviews with responsible policy makers, using a standardized questionnaire for collecting information on each of the policy-directed instruments.
- Performance indicators which provide comparable quantitative information on the performance of biotechnology innovation systems in all the countries involved. The analysis is based on the elaboration of indicators that cover both the knowledge base and valorisation and commercialisation.
- Qualitative and semi-quantitative cross country analysis of dynamics in biotechnology policies and policy effectiveness. For the evaluation of policy effectiveness the data on policy profiles in 1994/95 based on the Inventory project (Enzing et al. 1999) and elaborated in the Polybench project (Reiss et al. 2005) and policy profiles in 2001 provided by the Epohite project (Reiss et al. 2003) are used against the performance data for 2004 collected by BioPolis. For the analysis on policy dynamics the data on policies in 1994-1998 of the Inventory (Enzing et al. 1999) were also used.

The categorization of biotechnology stimulating policies and the performance indicators used will be presented in more detail in the rest of this section.

### 2.3.1 Categorisation of policies and policy-directed funding

Governments can use a broad set of instruments to stimulate biotechnology, as biotechnology activities cover a large part of the innovation chain: from basic research to market demand. For instance a research programme is a policy instrument as it constitutes a framework of goals to be achieved and serves as a basis for defining and planning specific research projects. Other examples are programmes that encourage collaboration between academia and industry, industrial research grants, support for centres of excellence, support for commercialization of research, support for start-ups, programmes encouraging mobility of researchers, etc. A policy instrument can be a funding mechanism, but also a set of rules, laid down in legislation (such as IPR). BioPolis includes only policy instruments that implements policies through funding mechanisms, excluding tax measures.

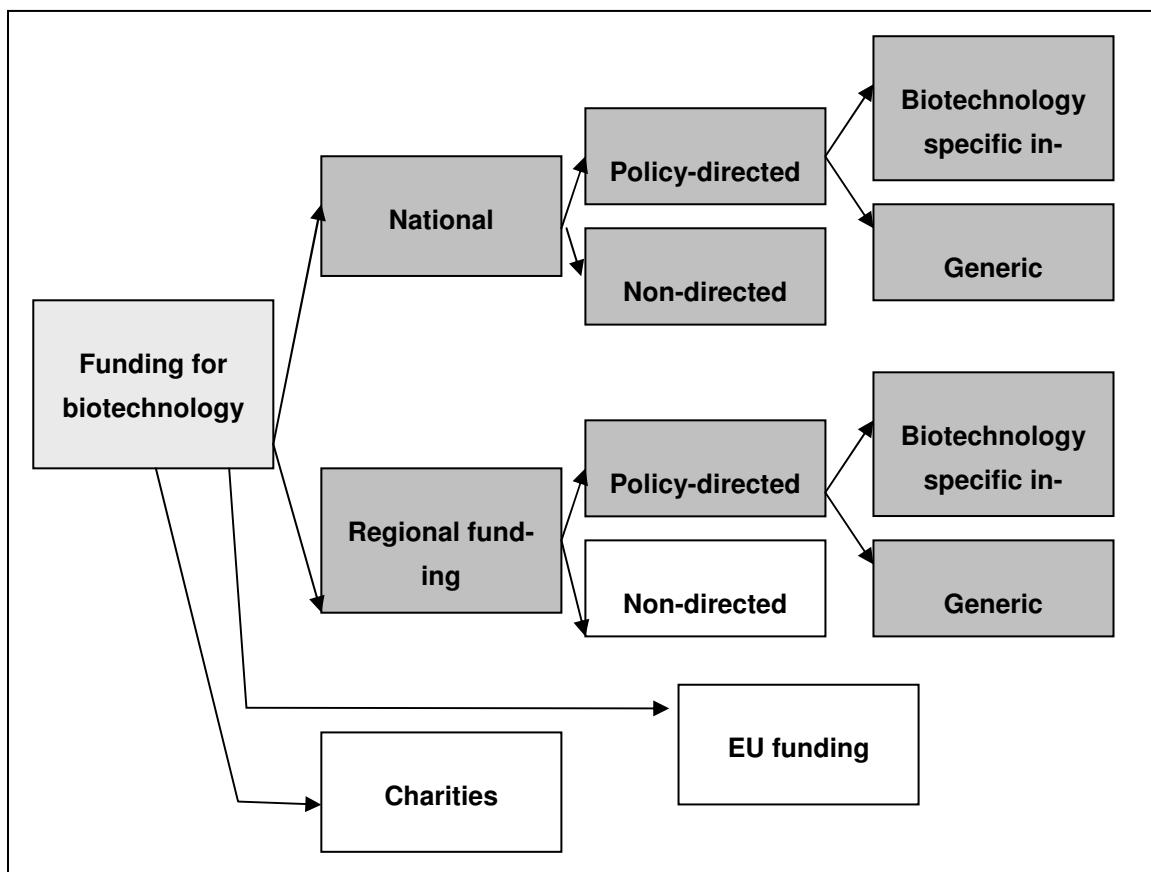
Similarly to the Inventory project (Enzing et al. 1999), BioPolis differentiates between those policies specifically designed to target biotechnology and those with a generic character. **Generic policies** are not targeted at a specific technology, but can contribute to the development and commercialisation of biotechnology. Governments have **biotech-specific policies** when the government has the

intention to influence some development in biotechnology and this policy is described by its general ideas, policy goals, target groups, etc in a policy document<sup>4</sup>.

Accordingly, national and regional governments use policy-directed instruments to implement their policies. Biotech-specific policy instruments are used to implement biotechnology policy; generic policy instruments are used to implement generic policies. Biotechnology policy goals can be covered by both biotech-specific and generic instruments.

Although BioPolis focuses on policies and policy effectiveness, as in the Inventory (Enzing et al. 1999) in the collection of funding data, so-called non-policy directed funding of biotechnology by national governments has also been included. The main reason for this is that in some countries funding through policy instruments is a relatively small part of biotechnology funding and non-policy directed funding is the most important funding mechanism for biotechnology. Figure 2.2 provides an overview of the funding structure of biotechnology activities. The shaded boxes show the instruments and funds that have been included in BioPolis.

Figure 2.2 Funding structure for biotechnology



Source: BioPolis Research

<sup>4</sup> Epohite (Reiss et al. 2003) uses 'vertical' for biotech specific, and 'horizontal' for generic.

Non-policy directed funding includes funding which is part of structural governmental support for scientific education, research and research infrastructure. This type of funding is mainly given through block grants to (government) research institutes, the open-call system of research councils et cetera. Basic funding for universities is not included. Research councils, research institutes and government research institutes may develop their own programmes through which biotechnology is supported. In order to provide comparable data on the funding of biotechnology for each country, both policy-directed and non policy-directed funding were included.

Data on funding by charities have also been collected and presented in the National Reports, but are not included in the overall analysis in this report.

A guidebook was developed that included the definition of biotechnology, an overview of relevant actors in the national biotechnology innovation systems (to be found in Annex 3), a data collection sheet for policy instruments, data sources and suggestions for data validation. All data on policy instruments were fed into a common database to support analysis.

### **2.3.2 The assessment of national performance**

Fourteen indicators were used to measure the performance of the national biotechnology system of innovation:

1. Biotech publications per Million Capita (pMC)
2. Biotech publications per biotech public R&D expenditure (only for EU15+3)
3. Biotech patents per biotech publication
4. Biotech publications as share of total number of publications
5. Citations to biotech publications
6. Graduates in life sciences pMC
7. Biotech patent applications pMC
8. Biotech companies pMC
9. Biotech start-ups pMC
10. Biotech Initial Public Offerings (IPOs) pMC
11. Venture Capital pC
12. Biotech acceptance index
13. Number of biomedicines
14. Number of field trials.

The indicators aim to capture trends in performance and to compare the national situation within a reference region. To present trends in performance most indicators are given for two or three or time periods (depending on data availability). To avoid capturing erratic trends, a time period includes several years (depending on data availability). See Annex 4 for an overview of the years that have been captured for the periods and comments concerning the index. Methodological issues related to some of the indicators are also addressed in Annex 4.

To benchmark each country, we have chosen the EU25 as the reference region (Romania and Bulgaria were excluded as they entered the EU only on January 1<sup>st</sup> 2007.) or the EU15, if data were not

available. In those cases where data for the EU25 or EU15 are not available, the reference corresponds to the sum of the national data available. Moreover, to ease the presentation of indicators with different scales in one chart, an index value has been used.

Data for all indicators - depending on data availability - are presented in Chapter 3 of the National Reports (in four charts: Knowledge base, Knowledge Transmission, Industrial Development and Market Conditions). The comparative analysis of country's performance is discussed for most of above listed indicators (Chapter 5 of this report). For the identification and comparison of country clusters with similar performance two indicators (1 and 5) were used to represent the performance 'Generating and sustaining a biotechnology knowledge base' and three indicators (7, 8 and 11) to represent 'Commercialisation of biotechnology'. Analysis of specialization patterns (based on publications by biotech area) have also been reported (Chapter 3 of National Reports and Chapter 4 of this report).

Although the methodology was carefully chosen in order to collect comparative data and was documented in a Guidebook used by the members of the project team, there were still several pitfalls. For instance, the number of countries using the OECD definition of biotechnology (mostly company surveys) is increasing but many countries do not yet apply this definition. Complete comparability was also obstructed because there was a tendency for different interpretations of definitions to be made both by members of the project team and by the representatives of the funding organizations that provided the data. In addition, data coverage is incomplete, as no data could be collected for some instruments. Nevertheless, BioPolis offers a very comprehensive, systematically formatted overview of biotech-related policy initiatives in European countries. The combination of input and output information and related benchmarking of countries presents a rich picture of policy and performance patterns across Europe.

### **3. National biotechnology policy-making systems in EU15+3**

#### **3.1 Introduction**

A country's scientific and commercial success in a given technology field is determined by a multiplicity of factors and legacies. The institutional setting constitutes an important part of the complex framework conditions influencing a nation's technological development. The purpose of this chapter is to provide an overview over the basic institutional configurations that are particularly relevant for the national biotechnology landscapes. As an all-encompassing presentation of every institution that relates to the development of biotechnology is not feasible, special emphasis is put on those areas which are involved in the processes of policy-making, the implementation of public policies, and the delivery of scientific and commercial results. The presentation of the general institutional patterns to be found in the EU15+3 is not to deny the broad range of institutional variety and the pronounced national differences which characterise the 18 individual country cases.

The main questions to be considered are:

- In which institutional settings – universities, research institutes, industry – is biotechnology research mainly performed?
- What are the institutional configurations – in terms of the number of relevant actors and veto players, the intensity of interactions – in which policy-making for biotechnology takes place?
- Closely related to the institutional structure of the policy-making systems are questions concerning the type and quality of national policy coordination mechanisms and the inclusiveness of decision-making processes.

#### **Outline of the chapter**

Prior to the presentation of the institutional patterns in EU15+3 (section 3.3), a brief introduction to the concept of the 'national innovation systems' approach (NIS) will be given (section 3.2.1). This general framework has not only inspired the conceptual approach of BioPolis, it also represents an appropriate point of departure for the ensuing analyses because its systemic perspective serves as a fruitful heuristic to grasp the complex interplay of institutions, collective actors and context conditions in innovation processes. Also, from the NIS-perspective, some of the most characteristic features of innovation processes in the area of biotechnology will be presented (section 3.2.2).

#### **3.2 The systems approach and biotechnology**

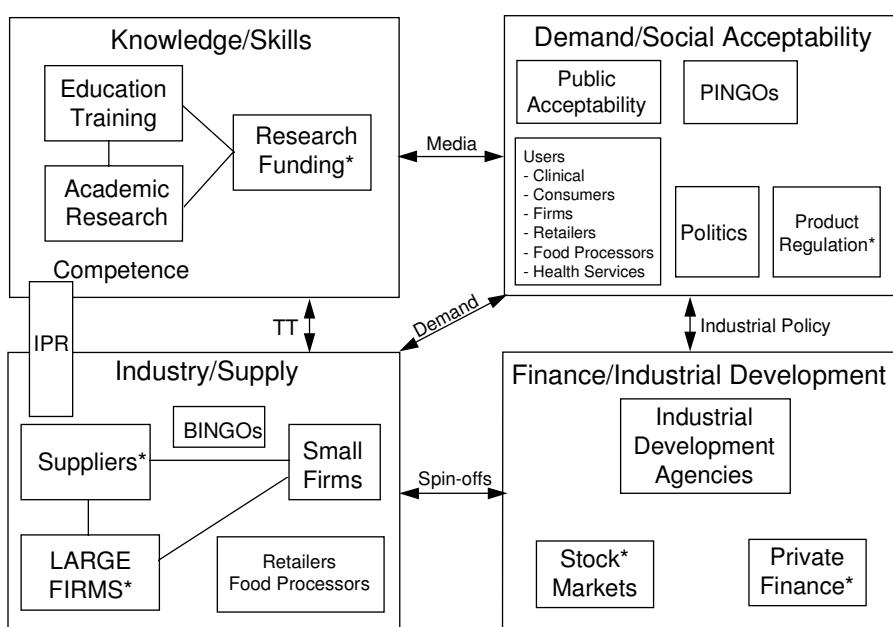
##### **3.2.1 Key factors influencing innovation**

A growing number of contemporary innovation studies is rooted in the basic 'national innovation systems' (NIS) approach. The shared understanding of this analytical framework is that innovations emerge in systems in which different actors and institutions are involved in interactive, interdiscipli-

nary and interdependent processes.<sup>5</sup> The NIS-approach highlights the complex interplay of different institutions and collective actors, and it is sensitive to unique national developments, the structuring role of historic legacies and path dependencies. Thus, in contrast to approaches based on neo-classic economic theory, the NIS-approach does not seek to develop a model of an optimal innovation system. However, the heuristic provided by NIS helps to identify deficiencies, bottlenecks and loopholes in national innovation processes. Based on an analysis instructed by NIS, recommendations for improvements can be developed.

Figure 3.1 shows a simplified model of the key elements of and the interconnections within a stylised national innovation system. The four main components of the system are (1) networks of knowledge and skills, (2) demand and social acceptance, (3) industry and supply, and (4) finance and industrial development.

Figure 3.1 Key elements and factors influencing innovation



\*International influence

TT = technology transfer; IPR = Intellectual Property Rights; PINGOs = Public interest non-government organisations; BINGOs = Business interest non-government organisations

Source: Senker et al. (2001: 20).

5 Within the general framework of the NIS-approach, different definitions, divergent theoretical arguments and analytical perspectives are being debated. The main representatives of NIS include Edquist, C. (ed.) (1997): *Systems of innovation. Technologies, institutions and organizations*, London, Washington; Lundvall, B.-Å. (ed.) (1995): *National systems of innovation: towards a theory of innovation and interactive learning*, London; Freeman, C./ Soete, L. (2000): *The economics of industrial innovation*, Cambridge, Mass. (3<sup>rd</sup> edition); Nelson, R. R. (ed.) (1993): *National innovation systems. A comparative analysis*, New York, Oxford; Porter, M. E. (1998): *The competitive advantage of nations*, Basingstoke, Hants; New York, NY.

The central features of these key components can be summarised as follows:

1. Knowledge and skills: includes the quality of publicly financed (basic) research, the knowledge-base, the degree of interdisciplinarity of R&D, education and training requirements, availability of a qualified workforce, knowledge and technology transfer within and between different sectors;
2. Demand and social acceptance: embraces market conditions (e. g., market approval, accreditation, regulation), diffusion rates of new products and services, acceptance and knowledge on the demand side, political conditions (policy coordination, degree of inclusiveness, fragmentation), purchasing power, social conditions (technology affinity, orientations and values), public procurement;
3. Industry and supply: includes the degree of application of new technologies and methods, capability and disposition of industrial actors to cooperate, effectiveness of regional clusters, international exchange, transparency and availability of relevant market information;
4. Finance and industrial development: embraces the availability of (venture) capital, the structure and degree of internationalisation of the financial market, the support structures for business development.

The systems perspective emphasises that successful innovation systems are not only characterised by similar performance levels of its constituent elements but also by a high degree of interconnectedness and dynamic interactions between the different subsystems.

### **3.2.2 Innovation processes in modern biotechnology**

The NIS-perspective, in which different actors and their functions are interconnected during the processes of knowledge creation, exploitation and valorisation, fits well with the main characteristics of biotechnology as such: modern biotechnology is highly complex and involves a broad range of different actors whose functions and performances are interrelated. This technology provides many examples of the dynamic relationship between knowledge creation and commercial exploitation, and the impact of framework factors such as industry structures, financial markets, regulatory regimes and socio-cultural conditions (McKelvey et al. 2004: 44).

The literature dealing with innovation processes in biotechnology offers an impressive volume of empirical details. Some of the most notable generalisations derived from these empirical analyses will be presented in the following. Four stylised facts about modern innovation processes in general will structure the specific findings on biotechnology.

- Innovations are complex processes involving knowledge and markets

Modern biotechnology combines a broad range of scientific disciplines, techniques and methods. The degree of interdisciplinarity in the area of biotechnology is particularly high; potentially relevant scientific fields involved are, among many others, biochemistry, microbiology, bioprocess engineering, genomics, bioinformatics, nanotechnology etc. A large part of the scientific and technological developments in the field are driven by the internal logic and the interplay of these different disciplines.

Moreover, one of the specific features of innovation processes in biotechnology is the high significance of close linkages between scientific developments on the one hand and actual innovations on

the other. The knowledge created by basic scientific research is the immediate prerequisite for many industrial applications. In fact, this is illustrated by the characterisation of the biotechnology industry as highly knowledge-intensive and science-based. The intellectual distance between biotechnology research and its application is at times quite short.

Innovation in biotechnology clearly does not follow the outdated 'linear model'. As developments in science and commercial exploitation are separate but parallel processes involving numerous feedbacks and crossovers, innovation in biotechnology should rather be viewed as a dynamic and uncertain process in which many actors, variables and diverse framework conditions all feed into the equation.

- New scientific and technological areas create economic value in various ways and in different spatial dimensions

Due to the high degree of complexity in biotechnology innovation processes there is usually no direct relationship between a specific scientific breakthrough or technological solution and a commercial application. A certain discovery may in fact lead to a broad range of very different applications. Those organisations or firms intending to make use of such a new finding or newly developed method are faced with the challenge to access, adequately convert and apply the necessary knowledge.

As biotechnology matures, a developmental asymmetry between well known areas on the one hand and sectors that are in a rather early phase of scientific progress on the other will become more and more apparent. These diverging developments mean that certain, more developed areas will be characterised by relatively straightforward industrial adaptations, whereas less developed areas will have to put more emphasis on experimentation, thus facing a higher degree of uncertainty.

- Innovation processes are affected by actor networks as well as by social institutions

Many studies on biotechnology have underlined the importance of collaborative relationships – between companies, universities, research institutes. These networks, in which knowledge is collaboratively created, exploited and commercialised, are composed of diverse actors, ranging from individual scientists to research organisations, from firms to banks and from public decision-making bodies to research promotion agencies. Depending on the configuration of these networks and the specific situation, the public and private actors involved might complement each other with regard to the innovation processes, while in other instances they might rather be viewed as competitors.

Another specific characteristic of modern biotechnology is the dominant role scientists play during the entire innovation process. Scientists are particularly crucial with regard to the commercialisation of biotechnology. This is reflected, for instance, by the strong linkages biotechnology firms usually maintain with the academic community.

Innovation in biotechnology is also strongly affected by those institutions related to the regulatory sphere, ethics and public debate. In some of the most prominent biotechnology application areas, ethical issues and related public concerns about the potential impact on society are being publicly

debated. These debates affect actors in the field of biotechnology with regard to their perceptions of the future and may increase their uncertainty about the profitability of investments. In addition, legislation and regulation normally lags behind the developments in science and technology.

- Firms play an important role in knowledge exploration and exploitation

One of the most outstanding characteristics of biotechnology innovation is that firms are not only involved in the processes of commercialisation; in contrast to many 'old' technology fields, biotechnology companies are also actively engaged in research. The bulk of these activities are applied research, but some companies carry out basic research in their own laboratories and research institutes as well. Also, as has been pointed out previously, most firms are likely to collaborate with other firms, individual scientists, universities and research institutes in order to broaden their scientific and technological scope, recruit personnel, or reduce the financial burden of research.

In addition to the close relationships to other research performers, companies might also need to establish intensive linkages with their customers and potential end-users. This is especially important in those cases in which new products have to be trusted and accepted by users – most notoriously in the health care area – if they are to reach significant market shares.

The strong cooperation between sectors and the recurrent intellectual proximity between academic research and commercial application have facilitated the phenomenon of academic entrepreneurship. For these academic spin-offs, not only financial but also managerial support from venture capitalists and business angels is particularly valuable.

From a public policy perspective, these stylised features of biotechnology highlight the importance of pursuing a holistic approach to the promotion of this technology field as far as possible. Therefore, the coordination of relevant actors, institutions and policies is a decisive imperative for policy-makers.

### **3.3 Configurations of biotechnology policy-making systems in Europe**

The promotion of biotechnology has been on the agendas of all Old Member States since many years. The diversity of the numerous programmes, support schemes and policy instruments that have been implemented in the EU15+3 (see Chapters 4 and 6) does not only reflect different priorities as a response to the specific national performance profiles in biotechnology and the overarching political goals set by the governments, the national policy outputs and policy outcomes are also strongly influenced by the respective institutional configurations and the styles of policy-making.

In order to reduce the complexity of the national policy-making systems to a manageable level, the institutional relationships can be broken down into two chief dimensions:

1. The vertical dimension covers the institutions and actors involved in the initial decision-making process, the intermediaries responsible for the implementation of the policies and, finally, the addressees of the policies. However, contemporary policy-processes are characterised by numerous forms of interactions and feedbacks between these types of actors (Pal 2006: 6-13). For instance, during the actual decision-making process, both intermediaries and research performers

exert influence through formal and informal channels; similarly, attempts to exert influence are also common place during the implementation and performance phases.

2. The horizontal dimension relates to the interactions between institutions and actors situated on the same level. Responsibilities for the promotion of science and technology are usually distributed across several ministries, departments and agencies. Moreover, additional stakeholders may fulfil certain functions in these decision-making processes. Depending on the number of actors involved, the intensity of interactions between the relevant institutions and the dominant style of interest accommodation, different modes of policy-coordination emerge (Pal 2006: 12f.).

In order to set the scene, the most relevant institutions placed on the vertical dimension will be presented first. Based on the structural features of the institutional landscapes, the policy-processes will be discussed in terms of the intensity of interaction and the degree of inclusiveness.

The information and data used in the following overview are derived from the BioPolis national reports (see CD-ROM supplement) and additional qualitative assessments provided by the authors. The introductory chapter of each national report deals with the characteristics of the national S&T and innovation system, the national framework conditions for biotechnology and the biotechnology research landscape. Thus, the national reports provide information on the configurations of the research scenes, the policy-making systems and the institutional settings. In addition to the descriptive presentation of the relevant actors and institutions involved, the rather fuzzy issues of coordination and interaction between the actors are addressed as well. The qualitative assessments of the national policy-making processes are primarily based on policy studies and interviews with national experts. However, as the analysis and evaluation of the national biotechnology policy-making systems was not among the chief tasks of BioPolis, in some cases the appraisals are sketchy or merely implied.

It should be noted that the appropriation of the national cases to the various categories may at times represent rough approximations or estimates. The National Reports of BioPolis and the Inventory (Enzing et al 1999) deal with the national complexities in greater detail.

### **3.3.1 Configurations of national biotechnology research landscapes**

One of the distinguishing features of the national research landscapes is the institutional setting in which science is performed. Depending on historic trajectories and policy legacies, the relative importance of publicly funded universities, non-university research institutes and research performed in the private sector may differ considerably.

With regard to publicly funded research, some systems are dominated by universities, whereas other systems tend to allocate significant resources for research in non-university institutes. On a very general level, the two institutional settings may be characterised as follows:

- Research performed at universities may potentially benefit from synergetic exchanges between higher education and science. The research groups have access to a young, highly trained workforce; academic freedom and independence facilitate creativity and the pursuance of exceptional scientific endeavours.

- Even though publicly funded research institutes need not necessarily offer less academic freedom, the rationale of setting them up is often the strategic aim to strengthen a particular scientific field and/or basic or applied research activities. In addition, specialised institutes can utilise expensive equipment with greater efficiency than might be the case at some universities.

The importance of biotechnology related research performed by the private sector differs considerably as well. The general national patterns usually are reflected by industry's share of GERD (see chapter 7.2). However, notable variations are observable in those cases where a country's biotechnology industry invests – in relative terms – more or less than the national average. For instance, in international comparison, both the United Kingdom and Iceland reported industry shares of GERD of 42.2 % and 43.9 % respectively – values significantly below the EU25 level of 54.9 % (all 2004).<sup>6</sup> Yet, if the private sector's research performance in biotechnology in these two cases is examined, a quite different picture emerges, indicating that in both countries industry seems to be contributing more than one could expect based on the industry-wide data. Apart from the general fact that biotechnology is a particularly knowledge- and research-intensive industry, specific national industry configurations – e. g., overall maturity of the national biotechnology sector, market demand for biotechnology products and services, availability of capital – account for the observed variations.

Table 3.1 presents a rough overview over the weight of biotechnology research within each of the three main research performing sectors in each of the EU15+3 countries. Unfortunately, accurate and detailed data on the respective contributions of universities, publicly funded non-university research institutes and industry in biotechnology are not available. Thus, the displayed information is based on qualitative assessments derived from the BioPolis national reports.

Within the top-performing group, it can be observed that biotechnology research activities are concentrated both at universities and in the private sector. In most of these cases, non-university research institutes exist, but their contribution to the overall quantitative biotechnology output seems rather low.

In the medium performance group, the distribution of biotechnology research contributions by sector is fairly balanced. With the exception of the United Kingdom and Belgium, publicly funded non-university research institutes play a significant role in the national biotechnology research landscapes. In countries such as Germany or France for instance, this observation corresponds to the well known importance of the public institutes (e. g., the Max Plank and Fraunhofer Societies in Germany, and INRA and CNRS in France) in the national innovation systems. In the Austrian case, for instance, biotechnology research in non-university institutes has been actively strengthened by public expenditures in the past few years.

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<sup>6</sup> The data are taken from the Eurostat online database, structural indicators (URL: <<http://epp.eurostat.ec.eu.int>>, 29.11.2006).

Table 3.1 Importance of biotechnology research within performing sectors

	<b>Universities</b>	<b>Public non-university research institutes</b>	<b>Industrial research</b>
Iceland *	<i>medium</i> **	<i>low</i>	<i>high</i>
<i>Cluster 1</i>			
Switzerland	<i>high</i>	<i>low</i>	<i>high</i>
Denmark	<i>medium</i>	<i>low</i>	<i>medium</i>
Sweden	<i>high</i>		<i>high</i>
Finland	<i>medium</i>	<i>low</i>	<i>low</i>
<i>Cluster 2</i>			
Austria	<i>medium</i>	<i>medium</i>	<i>low</i>
United Kingdom	<i>high</i>	<i>low</i>	<i>medium</i>
Belgium	<i>medium</i>	<i>low</i>	<i>medium</i>
Netherlands	<i>medium</i>	<i>medium</i>	<i>medium</i>
Ireland	<i>medium</i>		<i>medium</i>
Germany	<i>medium</i>	<i>medium</i>	<i>medium</i>
Norway	<i>medium</i>	<i>medium</i>	
France ***	<i>medium</i>	<i>medium</i>	<i>low</i>
<i>Cluster 3</i>			
Italy	<i>medium</i>	<i>medium</i>	<i>low</i>
Spain	<i>low</i>	<i>medium</i>	<i>low</i>
Greece	<i>low</i>	<i>medium</i>	
Luxembourg	<i>low</i>	<i>medium</i>	
Portugal	<i>low</i>	<i>low</i>	

\* The 18 countries are ordered in three Clusters according to their performance in biotechnology (see chapter 5).

\*\* The table provides a rough indication of the weight of biotechnology research within each of the three main performing categories. A blank field denotes no or a negligible share of biotechnology research.

\*\*\* In France, a clear distinction between university research and public research institutes is difficult as many research units are composed of mixed teams.

Source: BioPolis Research

A common feature of the countries with a low record in biotechnology performance is a weakness in industry-based research. However, this observation corresponds to the general performance weakness in biotechnology; thus, it would be premature to call for public programmes to promote industrial biotechnology research without ensuring adequate investments in the knowledge-base.

### **3.3.2 National biotechnology policy-making systems**

Of the countless characteristics by which policy-making systems differ, two central dimensions are particularly interesting for the analysis of the policy-processes concerning biotechnology in EU15+3:

1. The number of different actors involved in decision-making, policy-design and implementation,
2. The intensity of interaction between the actors as an indicator for the quality of policy coordination.

As the number of players involved in decision-making and implementation processes yields obvious implications for the task of policy-coordination, it is important to examine the interplay of the two dimensions.

In the following, the policy-making profiles in terms of the number of relevant actors and the interaction between them will be discussed separately. Based on these findings, the relationship between the size of the policy community and the quality of coordination will be dealt with.

#### **National participation profiles in policy-making**

Public policy-making in the area of science, technology and innovation may involve a broad range of policy-actors – parliaments and the relevant commissions, ministries and the subordinate bureaucracies, intermediary agencies and advisory bodies etc. In addition to the actors that formally participate in the policy-making processes, other actors may be involved informally. In short, the policy field is populated by a host of parliamentary factions, (coalition-) parties, governmental agencies, advisory bodies, interest groups, associations, social movements and so on.

The actual processes of policy-making are strongly influenced by the number and the type of actors participating, by the distribution of veto powers amongst these actors and the degree of policy-congruence. According to a rule of thumb it can be expected that the difficulties in reaching a consensus over a policy aiming to change the status-quo increase with a growing number of veto players involved and growing differences of the policy goals these actors seek to achieve (Tsebelis 2002).

The number of relevant actors in the field of biotechnology policy-making differs from country to country. On a general level, the basic configuration of the policy-making system is predetermined by a country's polity and the existing legal framework. For instance, some systems are characterised by rather centralised governments and majoritarian decision-making procedures, while in other countries institutional power tends to be distributed among a larger set of actors – both horizontally and vertically (Lijphart 1999). Within these relatively persistent institutional frameworks, national differences also become apparent with regard to the number of ministries that carry responsibilities related to biotechnology policy-making and the extent to which advisory bodies, agencies, sub-national authorities etc. participate in decision-making, policy-design and implementation. Needless to say however, that the processes of agenda-setting, policy-design and implementation do not only take place within the formal institutions settings. To a considerable degree, informal, at times latent mechanisms of coordination and policy-formation are at play.

Table 3.2 presents the most relevant actors involved in the processes of policy-making in the area of biotechnology by country. Again, the information is derived from the relevant chapters of the BioPolis national reports. In order to indicate how many and which ministries or departments are assigned with biotechnology related competencies and portfolios, the most significant national ministries are listed. In addition, the categories 'intermediaries'<sup>7</sup>, 'advisory bodies' and 'regional authorities' cover the most common actors typically involved in biotechnology policy-making. It should be noted that each of the three categories cover a very broad range of institutional variation. Advisory boards, for instance, exist in all EU15+3 countries at various governmental levels. However, their composition, degree of autonomy, mandates and ultimately their policy-influence differs considerably. In order to indicate the participation of the most important addressees of public policies aiming to promote biotechnology, the categories 'scientific community' and 'industry' are included as well.

The participation of parliaments and the respective committees are not listed explicitly as it can be assumed that the broad direction of governmental actions is based on parliamentary consent. The role of parliaments and the committees dealing with science, technology and innovation usually play a significant role during the early phases of the policy process and exert their influence particularly with regard to agenda and priority setting.

In most of the EU15+3 countries, a ministry responsible for education/science/research is directly involved in biotechnology related policy-making. The ministries of the economy (or similar portfolios) are the second most common departments participating in biotechnology policy-making. In some countries, such as the United Kingdom, The Netherlands, or Norway, the ministries of the economy orchestrate the public biotechnology policy. In ten countries, sectoral ministries participate as well; however, in most instances these rather specialised departments tend to supplement the broad strategic policy initiatives of their governments. The number of national ministries assigned with biotechnology related policy competencies ranges from merely two to four. The bulk of countries involve either two or three ministries.

In those countries where funding agencies or similar institutions represent an important channel for R&D support, intermediaries tend to be involved in policy-making at least to some extent. In most cases, the intermediaries are represented in the relevant decision-making bodies.

Similarly, the regional level constitutes a policy actor in all federal countries (Austria, Belgium, Germany, Switzerland, and Spain) as well as in those cases where the sub-national level has been assigned a limited set of competencies (e. g., Italy, France) or the United Kingdom where the devolved governments of Scotland, Wales and Northern Ireland were gradually given relevant responsibilities

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<sup>7</sup> Intermediaries are institutions positioned between the governmental agency formally carrying the overall responsibility for a public programme or policy instrument – mostly a ministry – and the addressees of the policy. The intermediaries usually are assigned with the administration of the programmes, deal with financial matters and supervise the activities related to the programme. Depending on the national science and technology promotion system, these functions are performed by research councils, funding agencies or special project managing agencies.

since the late 1990s. However, the extent to which sub-national actors exert significant influence on biotechnology related decisions varies considerably. The importance of regional authorities as policy players is particularly high in Austria, Belgium and Germany, and rather limited in Switzerland. By and large, the policy actors on the sub-national level usually tend to focus on regional economic development and commercialisation issues.

Table 3.2 National biotechnology policy-making participation profiles

	National Ministry	Inter-mediary	Advisory body	Regional authority	Scientific community	Indus-try
Iceland*	EDU, ECO	●			●	●
<i>Cluster 1</i>						
Switzerland	EDU, ECO	●	●	●	●	●
Denmark	EDU, SEC		●		●	●
Sweden	EDU, ECO, SEC	●			●	●
Finland	EDU, ECO, SEC		●		●	●
<i>Cluster 2</i>						
Austria	EDU, ECO, ITD, SEC	●	●	●	●	●
UK	ECO, SEC		●	●	●	●
Belgium	EDU, ECO, SEC		●	●	●	
Netherlands	ECO, EDU, SEC		●		●	●
Ireland	SEC, ECU, EDU		●			●
Germany	EDU, ECO	●	●	●	●	
Norway	ECO, EDU		●			
France	EDU, ECO, SEC			●	●	
<i>Cluster 3</i>						
Italy	EDU, SEC			●	●	
Spain	EDU, ECO, SEC		●	●		
Greece	ECO, SEC		●			
Luxembourg	ECO, EDU, SEC					●
Portugal	EDU, ECO, SEC		●			

\* The 18 countries are ordered in three Clusters according to their performance in biotechnology (see chapter 5).

● indicates formal or informal participation in policy-making (for instance due to membership in advisory bodies, councils etc.).

EDU = ministry of education/science/research (or similar); ECO = ministry of economy (or similar); ITD = ministry of innovation/technology/development (or similar); SEC = sectoral ministries/departments (e. g., agriculture, health, environment, energy, fisheries)

Source: BioPolis Research

Advisory bodies are involved in science and technology policy-making in most of the 18 countries. Yet, assessing the influence of each of these institutions on a comparative basis is very difficult. The respective legal position within the institutional landscape merely constitutes one indicator for the political weight of such an advisory body. In many instances, the high reputation of an advisory body – based, for instance, on the public perception of a high degree of political independence – seems to be more important than its codified rights. Moreover, in some countries several advisory bodies are involved at different levels of the policy process. Examples where high-level advisory bodies play a crucial role in exerting influence on the overall direction of public science and technology policies are Austria and the United Kingdom.

Capturing the involvement of representatives of the scientific community and industry in biotechnology policy-making is difficult as well. In some cases – as in Iceland, Denmark or Finland – participation of these important stakeholders is clearly institutionalised. In most other countries, the channels of participation and influence for these groups are not as apparent. Sometimes, representatives of industry and/or science happen to be members of advisory bodies, in other instances decision-makers actively solicit policy input from stakeholders. In short, appropriating the degree of policy participation of science and industry is extremely fuzzy. Nevertheless, the review of the BioPolis national reports suggests that the existence of professional biotechnology network associations that organise and connect stakeholders increases the chances of influencing policy decisions.

With regard to the total number of different relevant policy actors involved in a policy-making system, both the top performing group as well as the medium performers include cases where the number of actors is comparatively high (e. g., Switzerland, Denmark, Germany) and cases in which the degree of fragmentation within the policy community tends to be rather low (e. g., Sweden, The Netherlands). The low performance group, on the other hand, is consistently characterised by a low number of policy players involved.

Concerning the policy input of two stakeholder groups (scientific community and industry), a general trend across all three performance groups can be observed: a high biotechnology performance level seems to be associated with a high degree of stakeholder inclusion.

### **Policy coordination in EU15+3**

Of course, differences between policy-making systems are not solely based on the size of the relevant policy network or policy community. Another feature which is particularly important for the analysis of policy-making systems is the coordination of the actors involved. Within its respective jurisdictions and areas of authority, every policy actor is basically able to set its own agenda, define specific strategic goals and pursue its own interests. From a performance or efficiency perspective, a high degree of policy coordination between the relevant actors reduces the likelihood of diverging or even contradictory policies, overlap and bureaucratic friction on the one hand, and increases the effectiveness of the resources invested in a certain objective on the other.

An adequate proxy to measure the degree of policy coordination is the intensity of interactions between the relevant actors. It can be assumed that frequent interactions facilitate – but do not guarantee, of course – the mutual exchange of information and the formation of shared policy orientations.

Table 3.3 gives an overview over the estimated degrees of interaction between the policy actors of the national biotechnology policy-making systems. The information provided in this table is based on the relevant chapters of the BioPolis national reports and on additional qualitative assessments provided by the authors. For example, the comparatively low interaction intensity for the Austrian case is based on combined findings retrieved from policy studies, interviews with national experts and the interpretation of the general policy-coordination performance given by the author of the report on Austria. In this particular case, difficulties arose due to the institutional fragmentation within the policy area. A relatively large number of actors designed and implemented support schemes with at times overlapping objectives. In addition, information exchange and coordination appeared to have been impeded by rivalries between departments and agencies. Apparently, Austrian policy-makers came to similar conclusions because considerable measures were recently introduced in order to improve the situation.

In addition to the interaction between different public actors, the intensity of the linkages between public actors on the one side and private actors on the other is roughly estimated as well. In case of the five federal countries, the estimated degree of vertical interaction between national and regional public actors is presented as well. It should be noted, however, that the assessment of the interaction intensity is based on rough approximations. Moreover, the population size of a country exerts considerable influence on the ability of policy actors to exchange information and to participate in policy debates. Small countries do not only tend to have the advantage of geographic proximity, it can also be assumed that the likelihood of interaction and personal contacts is higher due to the smaller number of individuals involved in the biotechnology policy community.

Within Cluster 1, the interaction scores tend to be notably higher than in the two other country clusters. Particularly the three most outstanding countries – Iceland, Switzerland and Denmark – show very high rates of interaction in all categories.

In Cluster 2, the distribution of interaction intensities is not as clear-cut. Here, The Netherlands outperforms the other group members in terms of policy coordination – mainly due to the successful coordination activities of an informal biotechnology network. Medium interaction intensity has been identified in countries such as Germany, Ireland or Norway; and the least intensity has been observed in Austria, Belgium, and France. The low ratings particularly for these three last cases can be explained with very specific national situations. In Austria, the coordination between the large number of actors involved calls for administrative improvements which have been on the public agenda already since several years.

Table 3.3 Estimated degree of interaction between policy actors

	<b>Between national public actors</b>	<b>Between public actors and industry</b>	<b>Overall</b>
Iceland *	<i>high</i>	<i>high</i>	<i>high</i>
<i>Cluster 1</i>			
Switzerland	<i>high</i>	<i>high</i>	<i>high</i>
<i>regional level</i>	<i>medium</i>		
Denmark	<i>high</i>	<i>high</i>	<i>high</i>
Sweden	<i>medium</i>	<i>medium</i>	<i>medium</i>
Finland	<i>medium</i>	<i>medium</i>	<i>medium</i>
<i>Cluster 2</i>			
Austria	<i>medium</i>	<i>low</i>	<i>low</i>
<i>regional level</i>	<i>low</i>		
United Kingdom	<i>high</i>	<i>medium</i>	<i>high</i>
Belgium	<i>medium</i>	<i>medium</i>	<i>low</i>
<i>regional level</i>	<i>low</i>		
Netherlands	<i>high</i>	<i>high</i>	<i>high</i>
Ireland	<i>medium</i>	<i>medium</i>	<i>medium</i>
Germany	<i>medium</i>	<i>medium</i>	<i>medium</i>
<i>regional level</i>	<i>medium</i>		
Norway	<i>high</i>	<i>low</i>	<i>medium</i>
France	<i>medium</i>	<i>low</i>	<i>low</i>
<i>Cluster 3</i>			
Italy	<i>low</i>	<i>low</i>	<i>low</i>
Spain	<i>medium</i>	<i>low</i>	<i>low</i>
<i>regional level</i>	<i>low</i>		
Greece	<i>medium</i>	<i>low</i>	<i>low</i>
Luxembourg	<i>medium</i>	<i>medium</i>	<i>medium</i>
Portugal	<i>low</i>	<i>low</i>	<i>low</i>

\* The 18 countries are ordered in three Clusters according to their performance in biotechnology (see Chapter 5).

Source: BioPolis Research

The Belgian case is marked by the difficulties rooted in the federal structure and the frictions between the country's national groups; and policy-making in France, despite notable improvements, continues to be largely centralised and hierachic.

With one exception, the countries in Cluster 3 all display low interaction intensities. Only in Luxembourg, which can be seen as a special case due to its size, a medium interaction level between the policy actors has been observed.

In the vertical dimension, the interaction intensity between public authorities is either medium or low. However, the impacts of the quality of policy coordination between the different levels of government is largely dependent upon the degree of policy autonomy the sub-national level has been assigned. For instance, a lack of vertical coordination seems to be less grave in Switzerland than is the case in Germany due to the larger role the German Länder play concerning the public promotion of biotechnology compared to the Swiss cantons.

### **The inclusiveness of biotechnology policy-making systems in EU15+3**

In the previous sections, two chief dimensions of the national biotechnology policy-making systems in EU15+3 have been examined: the size of the relevant policy community and the intensity of interactions between the relevant actors as a proxy for the quality of policy coordination. Obviously, the two dimensions are closely interrelated because the transaction costs of coordination increase substantially with a growing number of policy actors. At the same time it can be argued that the involvement of a large policy community holds at least the potential of improving the policy process as such – due to the inclusion of different perspectives, information and knowledge, and due to the higher probability of developing a shared understanding and policy direction among the actors concerned.

The two dimensions are summarised and brought together in Figure 3.2. The vertical axis represents the size of the relevant policy community, and the horizontal axis indicates the interaction intensity between the players. Thus, regardless of the number of actors participating in a national biotechnology policy system, the degree of interaction between the actors may differ.

The 18 countries have been arranged on the two-dimensional field according to the respective qualitative assessments provided in the introductory chapters of the national reports. Again, it should be noted that the individual positions of the countries represent rough estimates due to the fuzzy nature of the concept of interaction intensity.

The group countries belonging to Cluster 1 (which are top performers in biotechnology; see Chapter 5) tend to share a comparatively high degree of interaction intensity, independently of the respective number of policy actors. Among the group of Cluster 3 countries (low performers) only Luxembourg fares quite well in terms of policy coordination. Cluster 2 countries are more or less evenly distributed between high and low levels of interaction intensity.

Figure 3.2 Qualitative characterisation of national policy-making processes

		Intensity of interaction	
		Low	High
Size of policy community	Many actors	Austria*	Switzerland**
	Few actors	Belgium*	Germany*
Many actors		Spain	Finland**
		Portugal	Netherlands**
Few actors		France*	Ireland*
		Italy	Denmark**
Few actors		Greece	United Kingdom*
			Norway*
Few actors			Sweden**
			Iceland**
Few actors			Luxembourg

\*\* high performer, \* medium performer (for details of the performance analysis see chapter 5).

Source: BioPolis Research

With regard to the size of the biotechnology policy communities, the findings seem to run counter to conventional wisdom and even theoretical statements. The analysis suggests that the number of relevant actors involved in the policy process exerts less influence on performance than the quality of policy coordination. This might be explained by the particularly complex nature of biotechnology innovation policy which necessitates a broad range of knowledge and expertise in order to be successful.

### Conclusions

Drawing conclusions regarding an optimal institutional design in biotechnology policy-making is not only difficult due to the multiplicity and interdependence of factors contributing to the successful development of a biotechnology knowledge-base and industry, but also because national particularities, traditions and routines need to be taken into account.

Keeping these general limitations in mind, some general comments about an improvement of institutional configurations and policy-making processes can be made:

- Reducing the sheer number of actors involved in the policy-process apparently does not constitute an end to itself. It is beyond dispute that a reduction of the number of ministries or governmental agencies carrying responsibility for the promotion of a technology field will contribute to the reduction of transaction costs, organisational friction and overlap. However, particularly due to the complex nature of biotechnology innovation processes, a broad and up-to-date information-base and the inclusion of different perspectives and expertise are important

prerequisites for the design of successful policies. Thus, while it might be expedient to concentrate competencies and portfolios within the governmental and bureaucratic core – by reducing the number of ministries and departments carrying responsibility for the promotion of biotechnology, for instance –, an enlargement and opening of policy-making arenas for the meaningful participation of non-governmental stakeholders – particularly representatives of the scientific community and industry, but also consumer groups – has the potential to significantly improve national policy-making processes.

- The number and type of actors and veto players involved in a policy arena is largely determined by the legal framework, institutional persistence and powerful interests (Schneider/Janning 2006: 64-75). Thus, reducing the number of actors – at least within the governmental-administrative core – is often not easily achieved. Alternatively, putting a stronger emphasis on policy network management with the aim of increasing the inclusiveness of policy-making processes has the potential to unfold improvements already in the short-term. A higher intensity of mutual information exchanges not only within government but also within a broader set of non-governmental actors involved in biotechnology fits well with the general characteristics of this modern technology. The emphasis on information exchange, consultation, policy deliberation and reflexivity may also help to mitigate potentially damaging conflicts within the policy community, contribute to the development of shared understandings, and eventually foster policy-learning. Moreover, improving the management of policy networks is an important contribution to a strengthened horizontal coordination of public policies affecting the biotechnology innovation chain.



## 4. Public funding of biotechnology in the Old Member States and Associated Countries

### 4.1 Introduction

In the 15 Old Member States and the Associated Countries, Norway, Iceland and Switzerland, (referred to as: EU15+3) many policy instruments and support schemes have been implemented in the period 2002-2005 that aim to encourage the development of biotechnology. This chapter presents an overview of the non-policy directed and policy directed funding of biotechnology in EU15+3 in this period.

First of all, in section 4.2, the funding of biotechnology in Europe is compared with funding of biotechnology in the USA and other countries outside Europe. In addition, the budgets for biotechnology research in EU15+3 are discussed in more detail; including both national and regional funding. Section 4.3 presents the priority biotechnology has in the EU15+3 countries from a funding perspective, and provides the shares of non-policy directed and policy directed (generic and biotech-specific) biotechnology funding in more detail. Section 4.4 analyses the choices governments have made in supporting specific policy goals, including research, commercialisation or other activities. In section 4.5 the national specialisation patterns in biotechnology are presented in terms of the funds allocated to specific biotechnology application areas (such as health biotechnology, agrofood biotechnology or industrial biotechnology) and publications output. In several countries charities are important funders of biotechnology research: section 4.6 presents an overview for EU15+3. Section 4.7 concludes with a summary of the main findings.

The policy instruments will be discussed for clusters of countries with similar performance (see Chapter 5); results for the individual countries will be compared with the median results for the EU15+3. The overview of public funding of biotechnology as presented in this chapter is not as complete and detailed as was desired. As already mentioned in Chapter 2, it appeared to be very difficult to collect full information about the funding of biotechnology in many countries. The data presented are in many cases an underestimate and, in some cases, may also represent a rough indication of the actual situation.

The funding data in this chapter are presented in US Dollar Purchasing Power Parity (1 PPP\$ is similar to 1 US Dollar). The PPP\$ takes into account differences in purchasing parities between the various countries and between different years. Normally, the PPP\$ is used to compare data on Gross Domestic Product (GDP). A specific PPP\$ for R&D expenditures is under discussion in international organisations, such as OECD, , because the price level for R&D can differ from the general price level within a country. However, a specific R&D PPP\$ is not yet ready and therefore the PPP\$ for GDP is used in this study. The PPP\$ ratio is calculated by the OECD, but also by the International Monetary Fund and Eurostat.

## 4.2 Non-policy directed and policy directed funding of biotechnology

### 4.2.1 Public funding of biotechnology in Europe compared with non-European countries

In 2005, the total public funding of biotechnology in all 32 European countries in this study amounted to 4 077M PPP\$ (3 540M EUR). In 2005, the total public funding of biotechnology for the EU15+3 amounted to 3 795M PPP\$ (3 445M EUR), including national and regional non-policy directed and policy directed funding of biotechnology.

The European budget was far below the public funding of biotechnology in the United States. In 2005, federal public funding of biotechnology in the United States amounted to 23 200M PPP\$, which is almost six times more than the EU15+3 funding. Canada, Japan, China, South Korea and Singapore are all behind Europe. Japan leads the Asian countries with 1 900M PPP\$ in 2005 and South Korea is in second place with 1 200M PPP\$. The public funding of biotechnology in Canada and Singapore is equal (600M PPP\$) while the public funding of biotechnology in China is the lowest (500M PPP\$)<sup>8</sup>.

When the absolute funding figures are corrected for the population of the countries, the picture changes considerably (Figure 4.1).

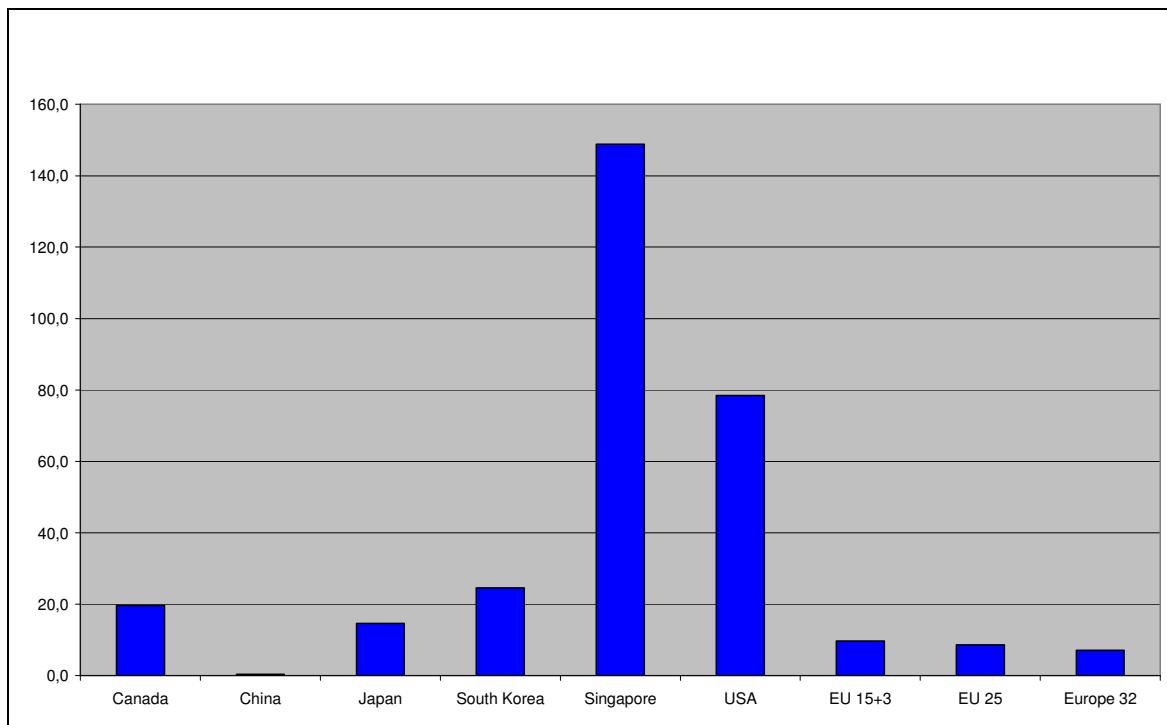
As shown by Figure 4.1, Singapore, with a population of approximately 4.4 million people, spent the largest amount on public funding of biotechnology per Million Capita (pMC). The United States is second with a budget pMC which is almost half the size of Singapore's. Nevertheless, the United States is far beyond Europe. For the EU32, the public funding of biotechnology pMC amounted to 7.1M PPP\$ in 2005. For EU15+3 public funding of biotechnology pMC amounted to 9.6M PPP\$ while EU25 reached 8.5M PPP\$.

In absolute numbers, Europe did better than the Asian countries and Canada, but when corrected for population, the latter were stronger. South Korea invested 24.6M PPP\$ pMC in biotechnology, followed by Canada (19.6M PPP\$) and Japan (14.6M PPP\$).

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<sup>8</sup> International comparison of public funding of biotechnology is very complex, mainly due to different definitions used for biotechnology used in the various countries and the inclusion or exclusion of regional funding (e.g. in the USA and Canada only federal funding is included). These difficulties may result in over or underestimates of the actual public funding of biotechnology. These figures, therefore, should be treated with caution.

Figure 4.1 Total public funding of biotechnology of the EU15+3, EU25 and EU32, USA, Canada, China, Japan, South Korea and Singapore in \$PPP pMC, 2005



Sources: Biopolis Research; USA: National Science Foundation (2006) Federal Funds for Research and Development: Fiscal Years 2003-2005, main category 'Life Sciences', including expenditures in the sub-categories 'biological sciences', 'environmental biology', 'agricultural sciences' and 'life sciences, nec'. The figure for 2005 is estimated on the preliminary budgets for 2004 and 2005; Canada: Delorey, C. and L. Lizotte (2006) Biotechnology scientific activities in federal government departments and agencies 2004/2005, Service Bulletin Science Statistics, Vol. 30 (2), SIEID, Ottawa; Statistics Canada; Japan: Japan Bioindustry Association (2004) Fiscal 2004 Government budget related to biotechnology, JBL, Vol 20 no. 4-5.; China: Stipp, D. (2002) China's biotech is starting to bloom, Fortune, September 2, 146(4), pp. 126-30, 132, 134, just expenditure on agrofood biotechnology; South Korea: Beuzekom, B. van and A. Arundel (2006) OECD Biotechnology Statistics – 2006; Singapore: Chan Sue Ling, (2005), Singapore's biotechnology push, International Herald Tribune, 18 September 2005.

#### 4.2.2 Total public funding of biotechnology in EU15+3 in 2002-2005

Table 4.1 presents the absolute figures for total public funding of biotechnology by the Old Member States and the Associated Countries in the period 2002-2005 (four years). In the period 2002-2005, total public funding by the EU15+3 amounted to 14 782M PPP\$ (13 431M EUR). This includes national and regional funding, both non-policy directed and policy directed instruments.

The Cluster 1 countries' public budgets for biotechnology are about the same size (136M to 147M PPP\$) except for Finland. Finland spent 3.5 to 4.5 times more on biotechnology than the other countries in Cluster 1. The public budgets for biotechnology differed greatly for the countries in Cluster 2, mainly because this cluster includes both very large countries with large budgets (Germany, France and United Kingdom) and smaller countries. Germany allocated the largest sum to biotechnology in 2002-2005 (4 876M PPP\$). France spent 40% less than Germany in the same period and the public funding of biotechnology in United Kingdom reached only one third of German expenditure. Of the smaller countries in Cluster 2, the Belgium government allocated the largest amount to biotechnology

(639M PPP\$), followed by the Netherlands and Austria. The smallest public budgets were provided in Ireland (228M PPP\$) and Norway (121M PPP\$). In Cluster 3 there is a sharp distinction between the two larger countries (Italy and Spain) and the smaller countries, Greece, Luxembourg and Portugal. Italy and Spain spent eight to ten times more on biotechnology than Portugal and Greece and the government of Luxembourg granted the smallest amount to biotechnology in EU15+3.

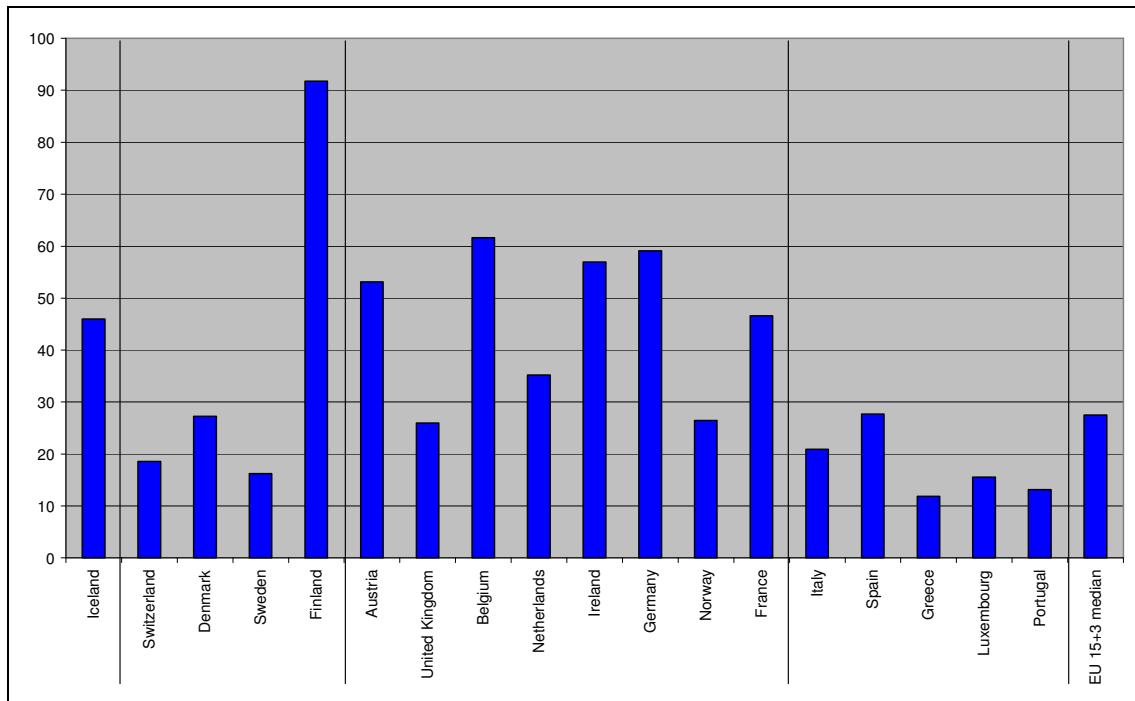
Table 4.1 Total public funding of biotechnology in the EU15+3 countries, 2002 to 2005

<b>Cluster</b>	<b>Country</b>	<b>Budget in M PPP\$</b>	<b>Budget in M EUR</b>
<i>Cluster 1</i>	Iceland	13	15
	Switzerland	136	156
	Denmark	147	166
	Sweden	145	146
	Finland	478	461
<i>Cluster 2</i>	Austria	432	389
	United Kingdom	1 545	1 444
	Belgium	639	562
	Netherlands	571	522
	Ireland	228	230
	Germany	4 876	4 575
	Norway	121	141
	France	2 810	2 543
<i>Cluster 3</i>	Italy	1203	1 014
	Spain	1162	875
	Greece	130	90
	Luxembourg	7	7
	Portugal	137	95
	<b>Total EU15+3</b>	<b>14 782</b>	<b>13 431</b>

Source: BioPolis Research

If the absolute funding figures are corrected for population size of the country (Figure 4.2) Finland outperforms the other EU15+3 countries with a total budget of 92M PPP\$ pMC.

Figure 4.2 Total public funding of biotechnology in the EU15+3, in \$PPP pMC, 2002-2005



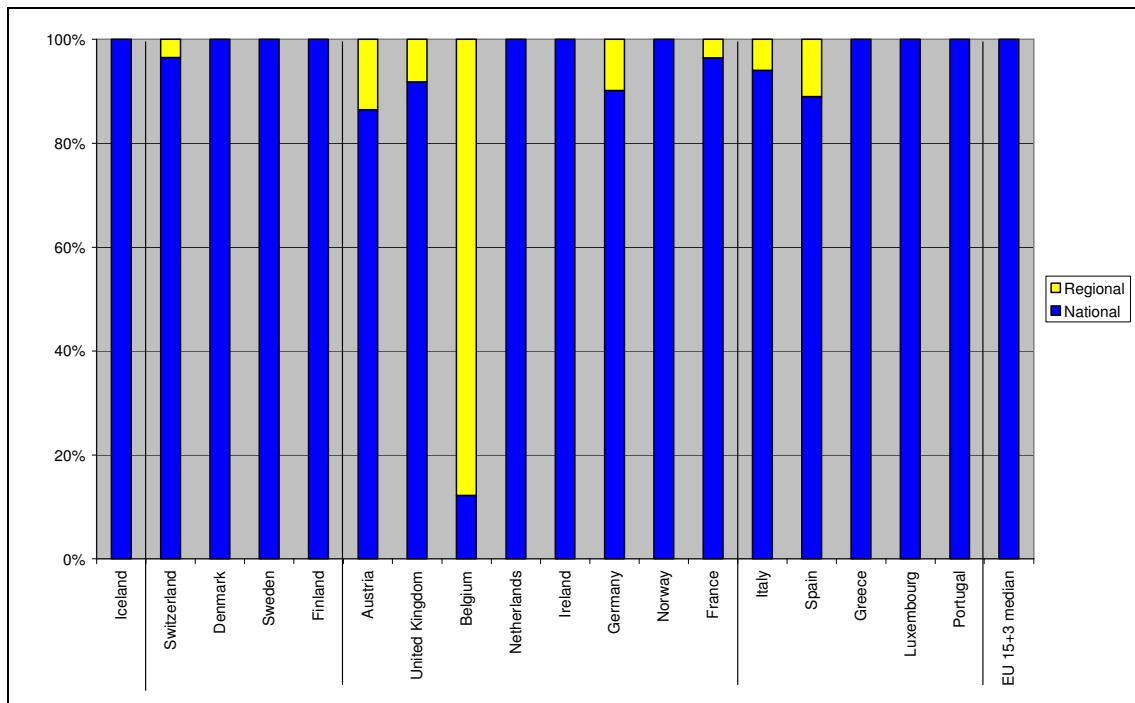
Source: BioPolis Research

Switzerland and Sweden in Cluster 1 spent less on biotechnology pMC than the median for EU15+3 and also less than the countries in Cluster 2. Denmark follows the EU15+3 median and Iceland reached the same level as the countries in Cluster 2. In Cluster 2, most countries allocated more funds to biotechnology than the median. The Belgian government spent the most in this Cluster; 62M PPP\$ pMC. Ireland, Germany, Austria and France followed close behind. The United Kingdom, third in absolute numbers, spent pMC almost the same amount as Norway, which was only second to last in absolute numbers. In Cluster 3, the Italian and Spanish budgets pMC were approximately similar to the EU15+3 median, but the other three countries granted substantially less pMC.

#### 4.2.3 Role of regional governments in funding of biotechnology

In eight European countries regional governments also provide funding for biotechnology. Figure 4.3 shows the share of regional funding in the total funding of biotechnology. In Belgium the regional governments were responsible for the largest share of total public funding of biotechnology: this amounted to almost 85%. However, Belgium is an exception in this respect. In Austria, Spain, Germany and United Kingdom, the share of regional government expenditure was between 10 and 15%. In Italy, France and Switzerland the regional share was below 5%.

Figure 4.3 Share of regional funding in total public funding of biotechnology in the EU15+3 countries, 2002-2005



Source: BioPolis Research

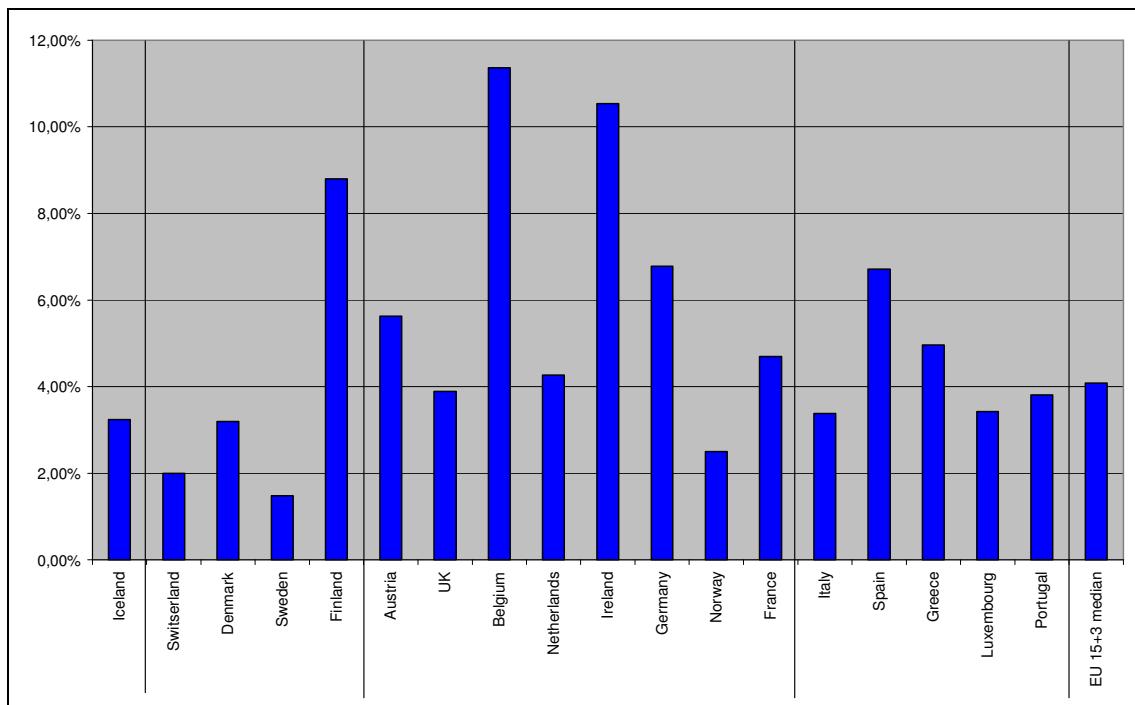
## 4.3 Importance of biotechnology in public policy making

### 4.3.1 Share of biotechnology funding in total government spending on R&D

The share of biotechnology funding in total government spending on R&D (GOV ERD) provides an indication of the priority given to biotechnology in national public policies. Figure 4.4 shows these figures for the EU15+3 in the period 2002-2005.

Biotechnology is certainly a priority in Belgium (11.4%), Ireland (10.5%) and Finland (8.8%). In the other countries in Cluster 1 biotechnology received a lower priority than the median in the EU15+3. In Cluster 2, Belgium and Ireland are followed by Austria and Germany. In Norway biotechnology was a lower priority than the median in the EU15+3; the United Kingdom and the Netherlands followed the median. Government funding for biotechnology in Spain and Greece in Cluster 3 was above the median; the other countries more or less followed the median.

Figure 4.4 Share of biotechnology funding in total public funding of R&D (GOV ERD) in EU15+3, 2002-2005



Source: BioPolis Research

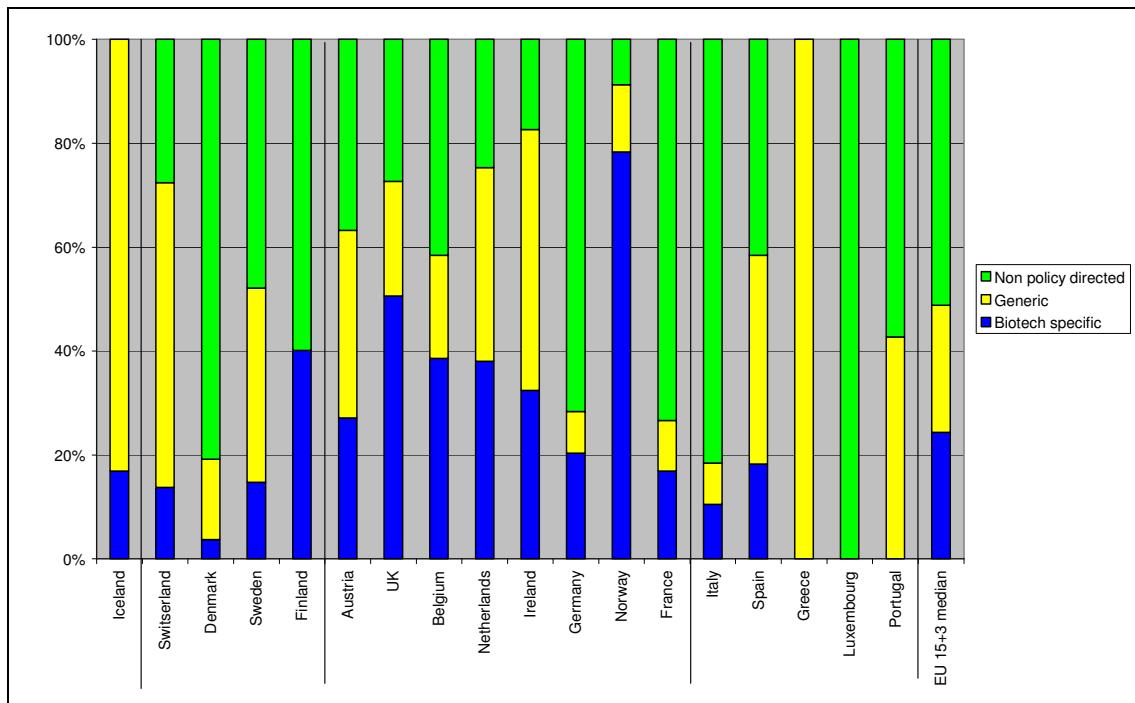
#### 4.3.2 Share of non-policy directed and policy directed funding in biotechnology

Figure 4.5 shows the share of non-policy directed, policy directed generic and biotech-specific funding in the period 2002-2005 for the EU15+3. In the EU15+3, the median distribution was 50% for non-policy directed funding; generic funding and biotechnology specific funding each had a share of 25%.

There is no consistent pattern for the division of funds through the different funding modes in Cluster 1 countries. In Denmark and Finland most of the funding was non-policy directed, but in Switzerland and Sweden generic instruments provided the largest sums. A considerable amount of funding was spent through biotech-specific instruments in Finland. In Cluster 2 there is also no consistency among the countries. The share of non-policy directed funding was the largest in Germany and France (70%), but the smallest in Norway (5%). In Norway, almost 80% of the funding for biotechnology was spent through biotech-specific instruments. However, this share could be lower in reality, as non-policy directed funding is an underestimate, due to lack of data about this type of funding for Norway. Also in the rest of the countries in Cluster 2, a considerable amount of biotechnology funding was granted through biotech-specific instruments (30 to 50%). Generic instruments were relatively important sources in the Netherlands, Ireland and Austria.

In Cluster 3, two countries - Greece and Luxembourg - fund biotechnology through a single funding mode only. Biotech-specific instruments only were available in Italy and Spain with a share of 10 to 20%. Non-policy directed funding was especially important in Italy and Portugal (60-70%). Generic instruments provided substantial amounts of funding in Spain and Portugal.

Figure 4.5 Share of non-policy directed, policy directed generic and biotechnology specific funding in total public funding of biotechnology in the EU15+3, 2002-2005



Source: BioPolis Research

These data, however, should be interpreted with caution as the distribution of funding by governments to non-policy directed research or to policy directed generic or biotech-specific instruments is affected by many factors. For instance, there will be a higher proportion of non-policy directed funding in national research systems that have a tradition of allocating block grants to research institutes (e.g. Germany, France and Italy) and those that base their activities on an approach where scientists decide the direction of research, and research proposals come in response to an open call for research proposals (Finland and Sweden).

With regard to policy-directed funding, government decisions to use generic or biotech-specific instruments are determined by several factors. In broad terms these factors cover:

- the maturity of the national biotechnology research sector;
- the range of biotechnology sub-sectors considered vital to support national interests;
- measures to address weaknesses in the national research system;
- market failure.

When a new area like biotechnology first emerges, countries wishing to build up national expertise and human resources in the area need to provide incentives so that scientists are ready to accept the risks inherent in being pioneers in the new field. It was therefore common during the 1980s and 1990s for countries to design biotech-specific programmes and instruments. When the field began to mature

and countries had built up capability in biotechnology, some decided that it was no longer necessary to treat biotechnology research as a special case. Biotechnology researchers could compete with those in other areas for funds available through generic instruments to promote research and commercialisation.

However, as it has matured, the biotechnology field has expanded rapidly, generating many new scientific sub-sectors, such as bio-informatics, genomics or proteomics. Thus each country has had to make decisions about the range of sub-sectors that are relevant to national interests. Some may decide to build up national capability in some or all of the new sub-sectors, and they design new biotech-specific instruments to meet this goal. Other countries may decide that national biotech needs are met better through the application of biotechnology to specific areas of national importance (for instance Denmark's biotechnology in food research programme, or Norway Aquaculture programme) and design either biotech-specific or generic instruments to meet this goal.

Evaluations of research performance may also explain the type of instruments designed by each country. For instance Austria recently introduced two major biotechnology-specific programmes in order to increase the public promotion of life sciences and biotechnology and Ireland began to support policy-directed basic research in biotechnology which was identified as one of its strategic priority areas.

Finally, governments may introduce either generic or biotech-specific programmes in response to aspects of market failure. For instance there may be programmes to encourage firms in traditional sectors to apply biotechnology to their products and processes (UK); various instruments to promote the innovativeness of small firms (Germany and Portugal) or providing seed capital for start-up firms (Finland, Iceland and The Netherlands).

## **4.4 Priorities in biotech policies for biotech research, commercialisation and other activities**

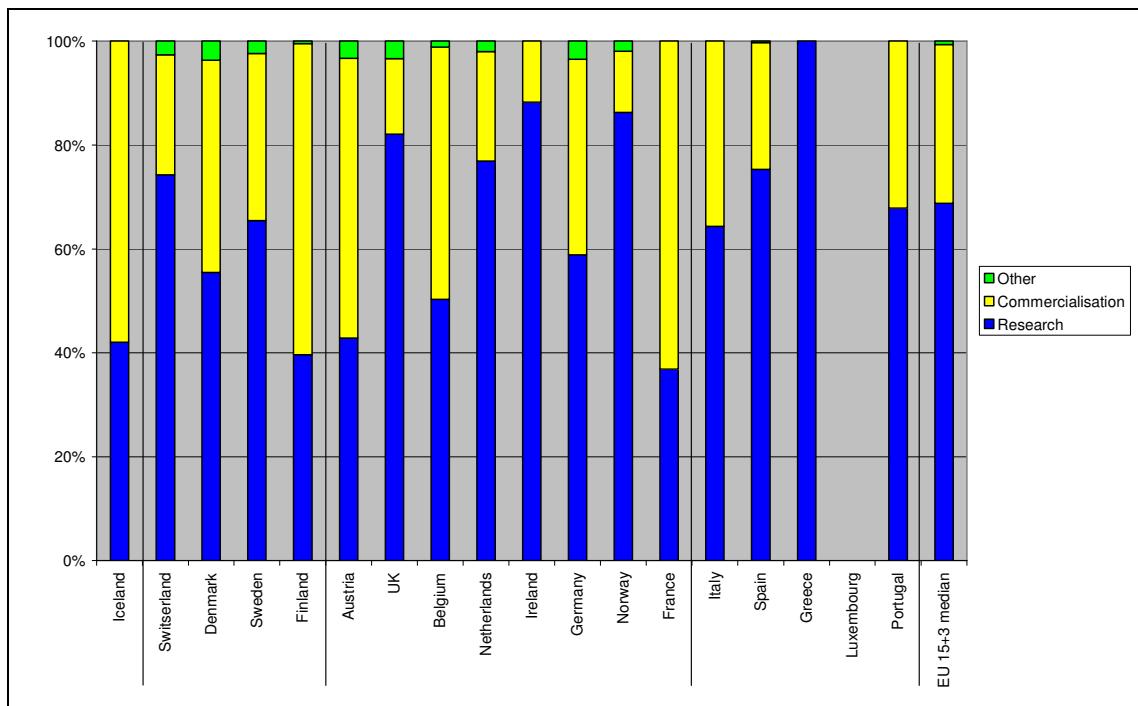
### **4.4.1 Priorities in policy directed funding for biotechnology research, commercialisation and other activities**

Governments aim to encourage various goals in biotechnology, with the main categories covering research and commercialisation. Figure 4.6 presents the division of public funding for biotechnology between research, commercialisation and other activities. It includes only the funding that has been spent through policy directed instruments.

In 2002-2005, according to the median, the EU15+3 spent almost 70% of biotechnology funding on research activities, 30% was spent on commercialisation and less than 2% was dedicated to the category 'Other'. Research funding supports high level biotechnology research, industry oriented and applied research, knowledge flow among scientific disciplines and the availability of human resources. Funding for commercialisation includes support and stimulation of knowledge flow from academia to industry, firm creation, adoption of biotechnology for new industrial applications and business invest-

ment in R&D. The category 'Other' includes funding for activities that enhance the public acceptance of biotechnology and activities that deal with biosafety issues.

Figure 4.6 Priority in policy directed funding of biotechnology for research, commercialisation and other activities in the EU15+3, 2002-2005<sup>9</sup>



Source: BioPolis Research

Research funding received the largest share in 13 of the 18 countries in the EU15+3. The Greek government's instruments focused fully on support for research activities. In Ireland and Norway, research had a share of 90% and, in most other countries, 60 to 80% of the funding was dedicated to research activities. There was more funding available for commercialisation than for research only in France, Finland and Austria. In 11 countries governments had developed instruments dedicated to social acceptance and biosafety issues, but they received small amounts only.

In Cluster 1, two countries (Switzerland and Sweden) granted 60 to 75% of biotechnology funding to research activities in the period 2002-2005. Finland, on the other hand, allocated about 60% of biotechnology funding to commercialisation. The countries in Cluster 1 spent less than 5% of funding on activities in the category 'Other'. In Cluster 2 six countries spent most of the funding on biotechnology research, with shares ranging from 50 to 90%. France and Austria, however, allocated more funding to commercialisation than to research activities. All the countries in Cluster 2, except Ireland, granted small amounts to activities related to biosafety issues and social acceptance. The countries in Cluster 3 granted at least 60% of funding to biotechnology research, with Spain dedicating the lowest share of

<sup>9</sup> Luxembourg is not included in the figure, as biotechnology is only supported through non-policy directed funding.

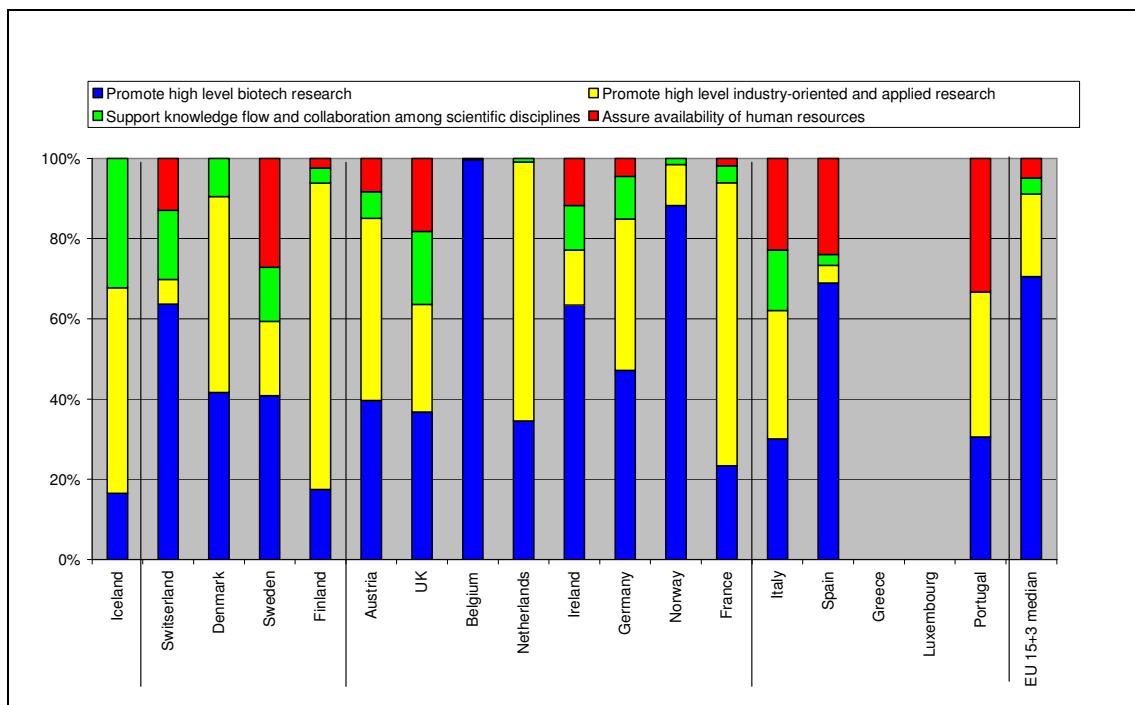
funds to commercialisation (25%). However, Spain was the only country in this Cluster that granted a very small amount to the category 'Other'.

#### 4.4.2 Share of research related policy goals in policy directed funding of biotechnology research

Figure 4.7 presents the research goals in more detail. It shows the division of policy directed funds between the various research-related goals within the total funding of biotechnology research. The percentages in Figure 4.7 should be read as merely indicative of the relative expenditure allocated to the various policy goals.

The median shows that the EU15+3 countries used approximately 70% of research funds for biotechnology to support high level biotechnology research. Almost 20% was granted to industry oriented and applied research, while 12% was used to support knowledge flow and 8% to assure the availability of human resources.

Figure 4.7 Share of research policy goals in the EU15+3, 2002-2005<sup>10</sup>



Source: BioPolis Research

There are rather large differences between the countries in Cluster 1. Switzerland spent a little more than 60% of the funds on high level research and only 5% was granted to applied research. In Finland, on the other hand, the share for high level research was just below 20% and approximately 70% of the Finnish biotechnology research funds were granted to applied research. Denmark used

<sup>10</sup> There are no data for Luxembourg because biotechnology was supported through non-policy directed instruments only. For Greece there are no data available about the funding attributed to the specific policy goals.

50% of the funds for applied research, while Sweden granted substantial amounts to the availability of human resources.

Figure 4.7 shows that Belgium, in Cluster 2, spent all biotechnology research funds on high level biotechnology research<sup>11</sup>. In Norway and Ireland this policy goal received most of the funds as well, but in other countries high level research received relatively less priority. Applied research received a high priority in three countries (Austria, France and the Netherlands). Scientific knowledge flow and collaboration was granted relatively smaller amounts, but was substantially supported in the United Kingdom (20%). Assuring the availability of human resources received the lowest shares, but again was granted substantial funds by the United Kingdom (20%). In Cluster 3 the profile also differs by country. In particular, Spain gave high level biotechnology research a rather high priority (almost 70%). Scientific knowledge flow and collaboration received only a relatively small share of the funds in Italy (15%) and Spain (less than 5%) and nothing in Portugal. Assuring the availability of human resources received more priority, especially in Portugal (35%).

#### **4.4.3 Share of commercialisation related policy goals in the policy directed funding of biotechnology commercialisation**

Figure 4.8 presents the commercialisation goals in more detail. It shows the division of funds over the various commercialisation related goals within the total funding of biotechnology commercialisation. Similarly to the research goals in section 4.4.2, the percentages in Figure 4.8 should be read as merely indicative.

The median of the EU15+3 shows that 45% of biotechnology commercialisation funds were used to facilitate knowledge transfer from academia to industry. About 20% was granted to the adoption of biotechnology for new industrial applications and 15% was used for supporting firm creation. Finally, 25% was dedicated to encouraging business investment in R&D.

In Cluster 1, supporting knowledge transfer from academia to industry was certainly a priority in Switzerland, but received relatively less funds in Finland. The Finnish government, on the other hand, gave priority to encouraging business investment in R&D and this policy goal received only small amounts in Switzerland. Firm creation was substantially supported in Switzerland, but in the other countries it received less priority.

In Cluster 2, six countries paid considerable attention to facilitating knowledge transfer, but in Belgium funding for this policy goal was absent<sup>12</sup>. In Norway, 80% was dedicated to stimulating the adoption

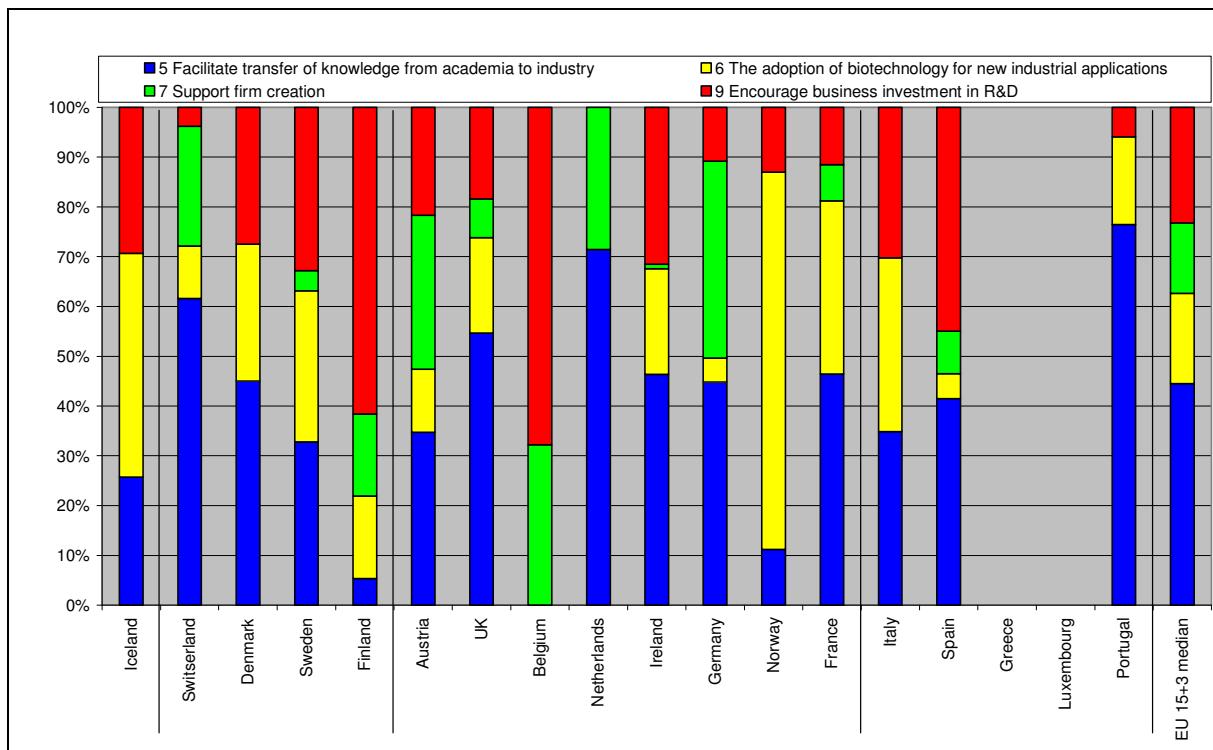
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<sup>11</sup> However, especially in Wallonia and Brussels, applied research and scientific knowledge were also supported through many different instruments. Unfortunately, lack of data makes it impossible to define the share of these policy goals in total biotechnology research funding.

<sup>12</sup> Nevertheless, especially in Wallonia and Brussels there were several instruments available that funded knowledge transfer from academia to industry. Lack of data made it impossible to define the amount of funds granted to this policy goal.

of biotechnology for new industrial applications. Also in France this policy goal received considerable funds (40%), but in other countries this policy goal was less important. Firm creation was granted substantial support in four countries (Austria, Belgium, The Netherlands and Germany), but in other countries this was really not a priority. Particularly in Belgium, biotechnology commercialisation funds were used to encourage business investment in R&D.

Figure 4.8 Share of commercialisation goals in the EU15+3, 2002-2005<sup>13</sup>



Source: BioPolis Research

In Cluster 3, Portugal spent 75% of commercialisation funds on knowledge transfer from academia to industry. Spain granted considerably more on encouraging industry to invest in R&D. Italy gave priority to the adoption of biotechnology for new industrial applications. Only Spain gave support to firm creation<sup>14</sup>.

#### 4.4.4 Share of biosafety and social acceptance policies in the policy directed funding of biotechnology

Figure 4.9 presents the extent to which promotion of public acceptance and research into biosafety issues is supported. It shows the division of funds over the two policy goals in the funding category

<sup>13</sup> There are no data for Luxembourg because biotechnology was supported through non-policy directed instruments only. For Greece there are no data available about the funding attributed to the specific policy goals.

<sup>14</sup> Italy had one regional instrument to support firm creation, but no data was available about the distribution of funds.

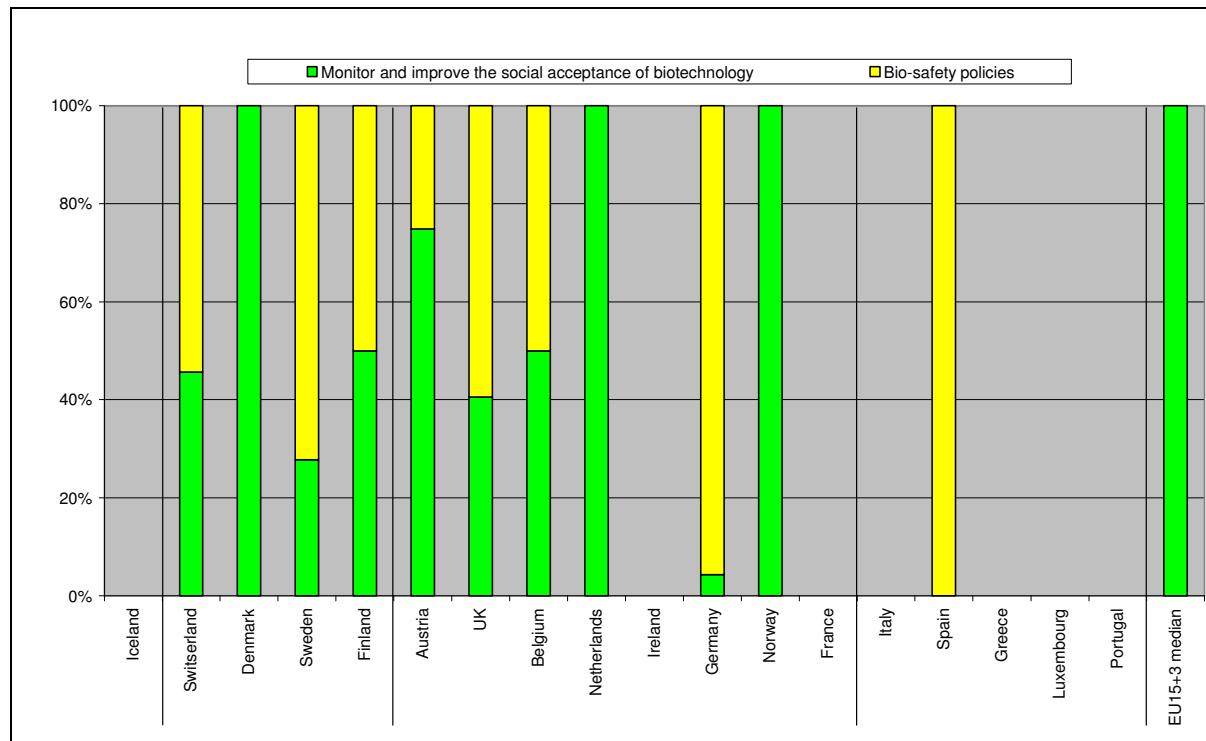
'Other'. Similarly to the research and commercialisation areas, the percentages in Figure 4.9 should be read as merely indicative.

Iceland did not spend any biotechnology funds on biosafety and public acceptance issues. In Denmark all funding in the category 'Other' was granted to monitor and improve social acceptance, while in Switzerland, Finland and Sweden 50 to 70% was used for biosafety issues.

France and Ireland (Cluster 2) did not allocate biotechnology funds to the category 'Other'. In Norway and the Netherlands all funds were spent on social acceptance and in Austria this amounted to 75%. United Kingdom and Belgium granted 40 to 50% of funds to social acceptance, while Germany allocated almost all its funds to biosafety issues.

In Cluster 3, only Spain granted funding to the category 'Other' and these funds were dedicated to biosafety issues.

Figure 4.9 Share of 'Other' goals in the EU15+3, 2002-2005



Source: BioPolis Research

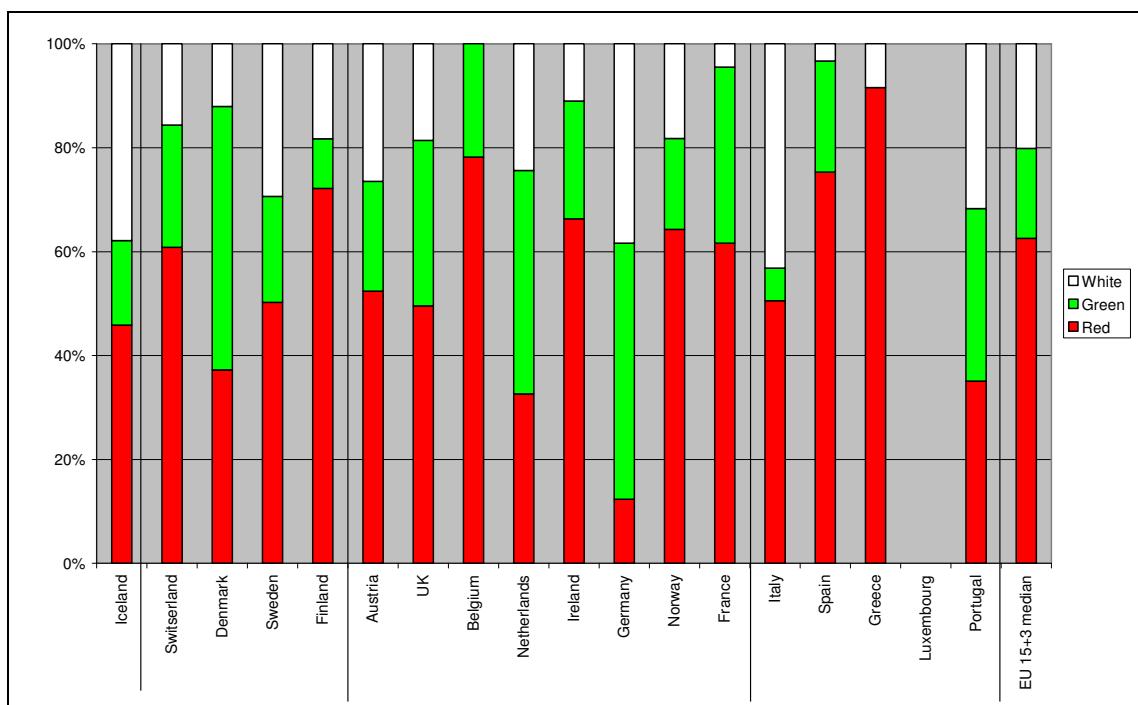
## 4.5 Specialisation patterns across Europe

### 4.5.1 Specialisation in Red, Green and White biotechnology

This section presents the specialisation of public funding for biotechnology in three main biotechnology research and application areas: Red, Green and White biotechnology. Red biotechnology covers health research and applications. Plant, animal and food research is included in Green biotechnology. White biotechnology covers industrial and environmental research and applications.

Figure 4.10 shows the relative distribution of funds in the three main application areas. It includes only data from the policy directed instruments. Luxembourg is excluded because only non-policy directed funding for biotechnology was provided for this country.

Figure 4.10 Public funding of biotechnology in three main application areas in the EU15+3 countries, in M PPP\$, 2002-2005<sup>15</sup>



Source: BioPolis Research

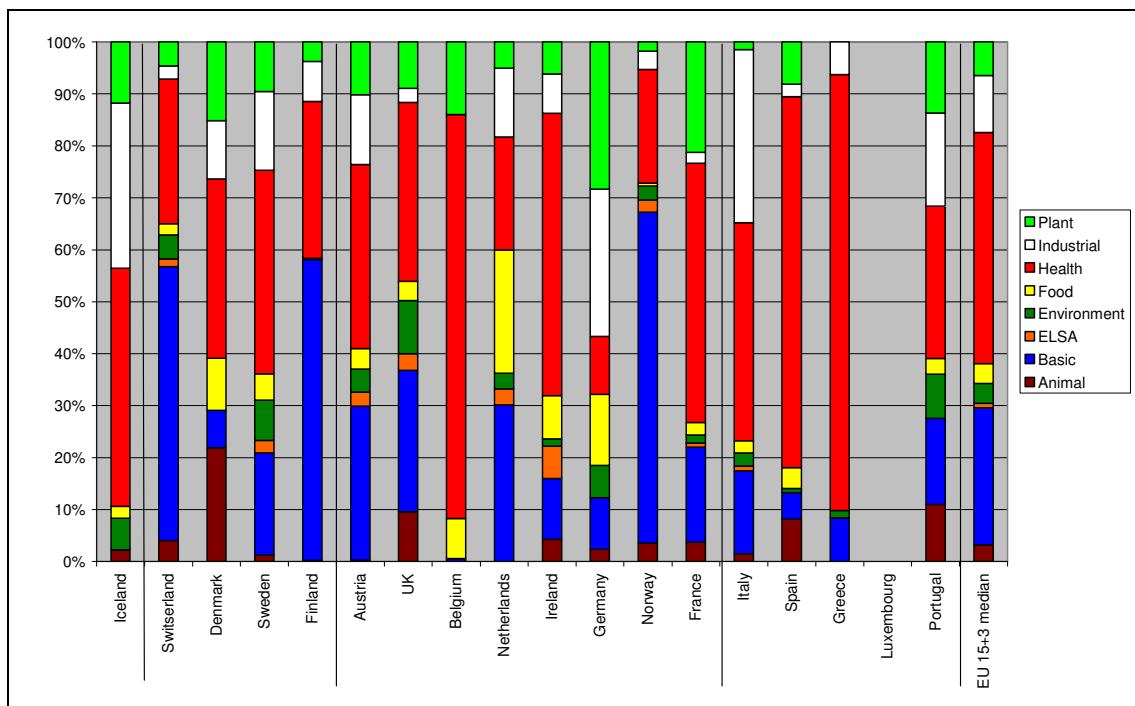
The picture is rather clear: in most countries (12 of the 17), Red biotechnology received the largest share of public funding in the period 2002-2005. In only five countries (Denmark, Germany, Iceland, the Netherlands, and Portugal) were the funds for Green plus White biotechnology related activities more than the funds for Red biotech. In 10 countries Green biotechnology received more funds than White biotechnology; in Iceland, Sweden, Finland, Austria, and Italy this was the other way around.

<sup>15</sup> There are no data for Luxembourg because biotechnology was supported through non-policy directed instruments only.

#### 4.5.2 Share of various application areas in public funding of biotechnology

More details about the share of the research and application areas in public funding of biotechnology are presented in figure 4.11. Besides Red, Green and White biotechnology, there are two other application areas: Basic biotechnology research and research related to ELSA issues (Ethical, Legal and Social Aspects).

Figure 4.11 Share of biotechnology application areas in public funding in the EU15+3 countries, 2002-2005<sup>16</sup>



Source: BioPolis Research

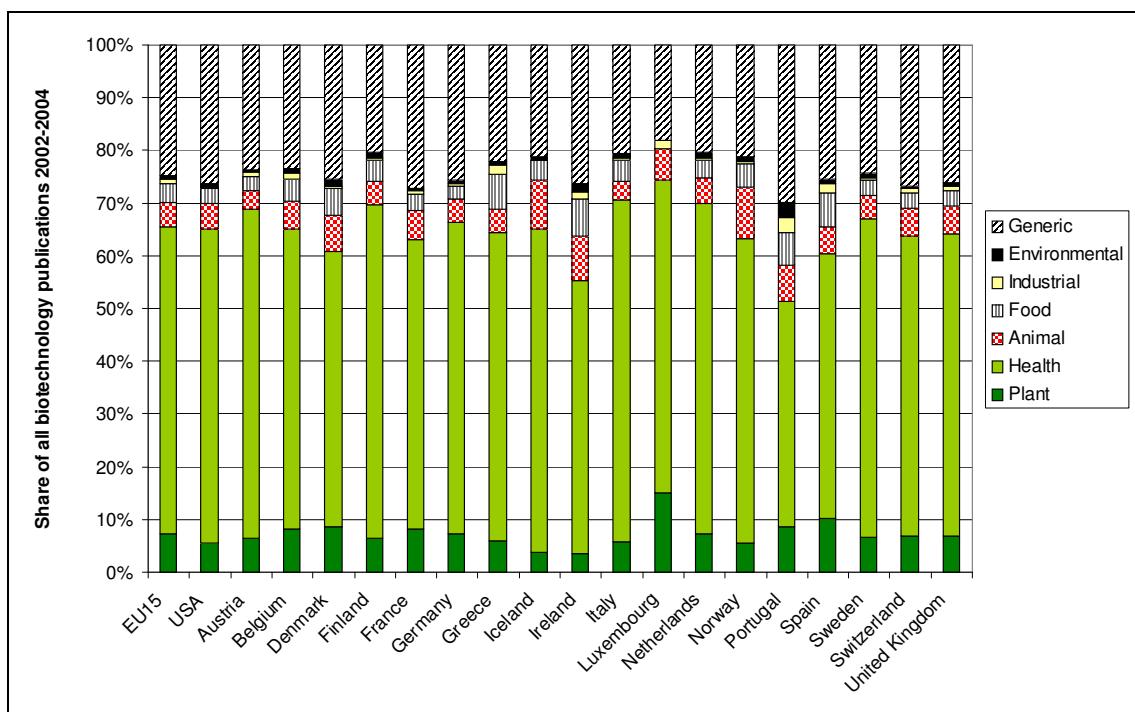
Basic biotechnology received substantial funding in Norway, Switzerland and Finland and, to a lesser extent, in the Netherlands, United Kingdom, Austria and Sweden. Funding for ELSA biotechnology research received only small amounts of public funding in nine of the EU15+3 countries. In Ireland, ELSA research had the relatively largest share of public funding.

The specialisation profile can also be based on the share of field-specific publications in all biotechnology publications. This specialisation analysis, presented in Figure 4.12, indicates that specialisation patterns in biotechnology, as measured by the share of field-specific publications in all biotechnology publications, is rather similar in all European countries.. All countries had the strongest focus on the health field followed by basic biotechnologies and plant biotechnology. Italy, Finland, Sweden, the Netherlands and Austria presented an even a stronger focus on the health sector than the Euro-

<sup>16</sup> There are no data for Luxembourg because biotechnology was supported through non-policy directed instruments only.

pean average. Portugal seemed to be least specialised in health biotechnologies among the European countries. On the other hand, Portugal showed the highest share of basic biotechnology publications. In the case of plant biotechnology Spain was clearly above the European average, while Ireland has the lowest value<sup>17</sup>. Among other areas, the high score of Norway in the area of animal biotechnology is remarkable. This might be due to the importance of (animal-based) aquaculture in Norway. Comparing the European specialisation pattern with the United States reveals a very similar specialisation. While 58% of the EU15+3 publications in biotechnology have focused on the health area, the respective share for the United States is 59%. In the case of basic biotechnologies the respective shares were 25% (EU15+3) and 26% (United States), and finally in plant biotechnology the EU15+3 share was 7% compared to 6% for the United States. Obviously there is no difference in the specialisation of scientific activities in biotechnology between Europe and the United States as measured by scientific output indicators.

Figure 4.12 Specialisation patterns of EU15+3 in sub-areas of biotechnology



The figure shows the ratio of publications in subfields of biotechnology to all biotechnology publications for the period 2002-2004

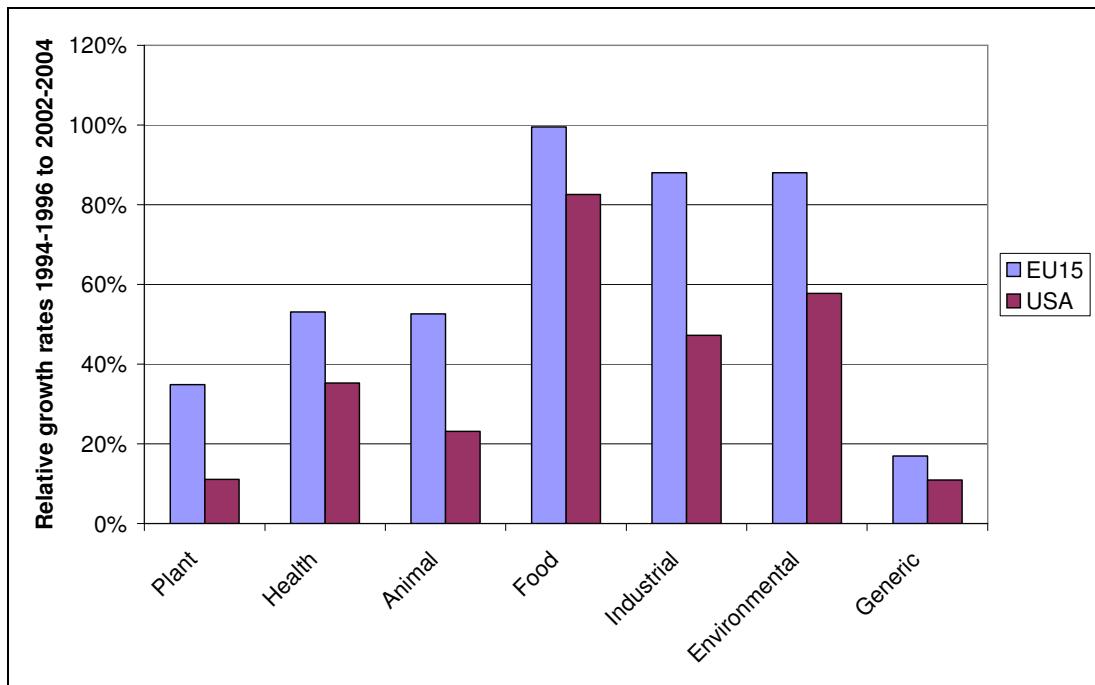
Source: BioPolis Research

In order to monitor changes over time in specialisation, the relative growth rates for each field were calculated for the EU15+3 and the United States (Figure 4.13). For both regions the strongest growth rates are observed for the smaller fields: food, industrial biotechnology and environmental biotechnology. The lowest growth rates are for plant biotechnology and basic biotechnology. Comparing the EU15+3 with the United States reveals higher growth rates in general for all fields in Europe. Since a

17 Due to low absolute figures, the data for Luxembourg are not considered in this discussion

similar absolute number of publications is observed in both regions, this difference cannot be explained by a size effect<sup>18</sup>. In particular, growth rates for the United States are much lower than for the EU15+3 in the field of plant biotechnology.

Figure 4.13 Specialisation trends in biotechnology across European countries and the United States between 1994 and 2004



Source: BioPolis Research

It is interesting to note that in many cases a strong focus on a specific field in publications is not related to a strong focus on a specific field in the funding of biotechnology. In Greece, Spain and Belgium, most of the funding was dedicated to health biotechnology, but these countries did not have a stronger focus on health biotechnology in their publications than other countries. In contrast, in the Netherlands, health biotechnology had a larger share of total biotechnology publications than the average for the EU15+3, but Dutch funding was more focused on food, plant and industrial biotechnology. There is a similar situation in Germany. Basic biotechnology had a relatively large share of the funding for biotechnology in Norway, Switzerland and Belgium, but basic biotechnology publications were stronger than average in Denmark, France, Germany, Ireland and Portugal. In Norway, Iceland and Ireland, animal biotechnology had a relatively large share in total biotechnology publications, but in terms of funding this area had a stronger focus in Denmark, Portugal, United Kingdom and Spain.

18 Higher relative growth rates would be expected in the case of lower absolute numbers

### 4.5.3 Share of Green and White biotechnology application areas

Table 4.2 shows the division of funds across the sub-fields of Green and White biotechnology. Green biotechnology includes food, animal and plant biotechnology. White biotechnology includes industrial and environmental biotechnology. Greece did not fund Green biotechnology in 2002-2005. Except for Belgium, Finland and the Netherlands, all the EU15+3 countries supported plant, animal and food biotechnology. Nevertheless, the division of funds between these three application areas differs among the countries. In seven of the EU15+3 countries plant biotechnology had the largest share in Green biotechnology funding. Food biotechnology received the largest share of funds in the Netherlands, Ireland and Italy. Animal biotechnology had the largest share in Norway, Spain, Portugal, United Kingdom and Denmark. In all countries except for Switzerland and United Kingdom, the funds for industrial biotechnology were substantially larger than for environmental biotechnology, and Denmark and Finland, allocated all White biotechnology funding to industrial biotechnology. Only Switzerland and United Kingdom gave the largest proportion of White biotechnology funds to environmental biotechnology, a share of between 60 and 80%.

Table 4.2 Share of Green and White biotechnology funding, in the EU15+3, 2002-2005

	Green biotechnology			White biotechnology	
	Plant	Animal	Food	Industrial	Environmental
Iceland	72%	14%	14%	84%	16%
<i>Cluster 1</i>					
Switzerland	43%	37%	20%	36%	64%
Denmark	32%	47%	21%	100%	0%
Sweden	60%	8%	32%	40%	60%
Finland	94%	6%	0%	100%	0%
<i>Cluster 2</i>					
Austria	71%	2%	27%	75%	25%
United Kingdom	40%	43%	17%	21%	79%
Belgium	65%	0%	35%	0%	0%
Netherlands	17%	0%	83%	81%	19%
Ireland	33%	23%	44%	84%	16%
Germany	64%	5%	31%	82%	18%

Norway	30%	60%	10%	55%	45%
France	78%	13%	9%	57%	43%
<i>Cluster 3</i>					
Italy	28%	28%	44%	93%	7%
Spain	40%	40%	20%	75%	25%
Greece	0%	0%	0%	81%	19%
Portugal	49%	40%	11%	68%	32%

Source: BioPolis Research

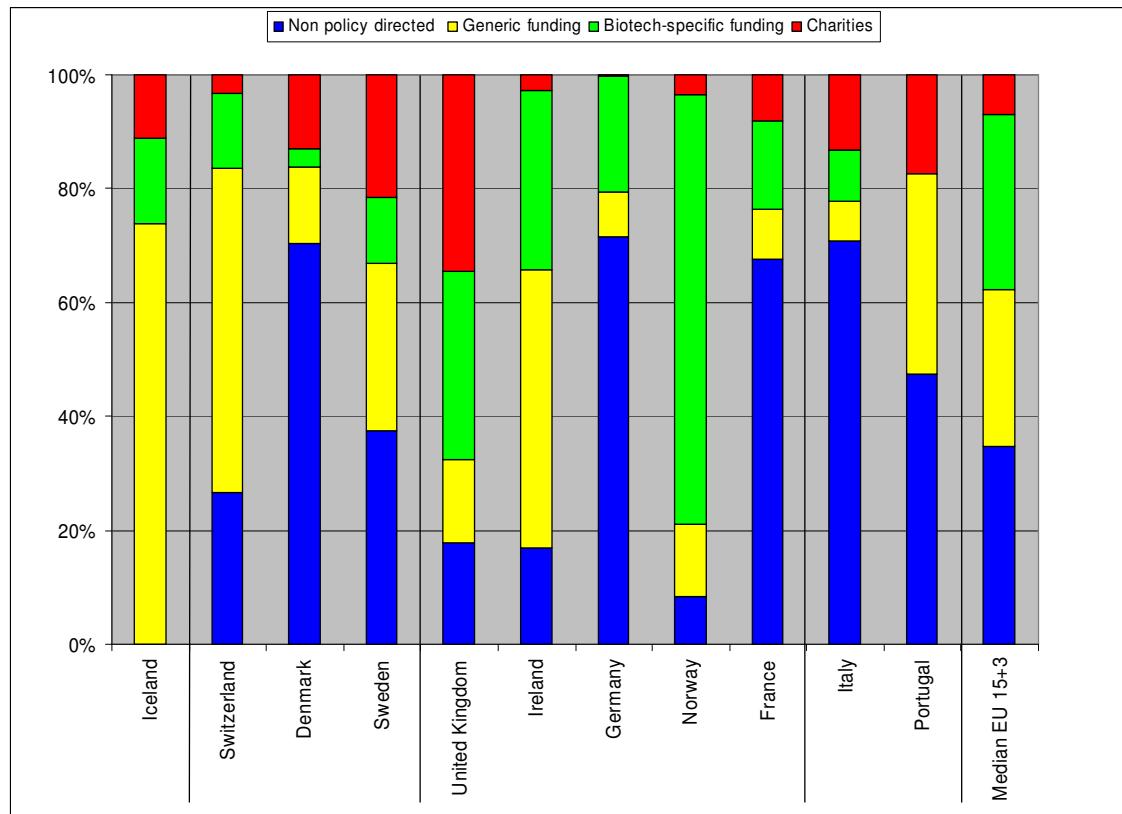
#### 4.6        Role of charities in funding of biotech research

In several countries government funding for biotechnology was supplemented by substantial funding from charities. This section presents the role of charities in funding biotechnology R&D<sup>19</sup>.

There is no consistent profile for the source of biotechnology funds across the clusters. Charities funded biotechnology research in 11 countries of the EU15+3 in the period 2002-2005. Although the largest share of funding for biotechnology came from the government in all countries, in some countries charities provided a substantial amount, particularly in United Kingdom. As shown in figure 4.14, in the UK 35% of the total funding of biotechnology is provided by charities. In other countries this was less, but still amounted to about 20% of the total funding in Sweden and Portugal. In Denmark, Iceland and Italy this share was approximately 15%. In France, Norway, Switzerland and Germany, this was less than 10%. Unfortunately, data about expenditure on biotechnology research were available not for all charities.

<sup>19</sup> In BioPolis charities are defined as independent non-profit organisations that fund research. This research can be performed in other research organisations such as universities, but in some cases this research takes place in their own research institutes.

Figure 4.14 Share of charities in total funding of biotechnology in the EU15+3 countries, 2002-2005



Source: BioPolis Research

Table 4.3 presents an overview of the charities that fund biotechnology research in the EU15+3 countries. In the EU15+3 countries at least 1 355M PPP\$ has been spent by charities on biotechnology research during the period 2002-2005<sup>20</sup>. The British charities provided the largest amount of funding for biotechnology research. These charities not only fund research in United Kingdom, but also in other countries. Substantial amounts of funding are also granted by charities in France and Italy. The main charities providing funds for biotechnology research include cancer societies and heart disease foundations. In Austria, Finland and Greece charities are not relevant for biotechnology research as they did not dedicate funds to biotechnology research during the period 2002-2005.

Table 4.3 Overview of charities funding biotechnology research in the EU15+3, 2002-2005 (in M PPP\$)

Country	Name of charity/ties	Funds for biotechnology
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<sup>20</sup> Although independent organisations, in some cases, charity organisations with their own research institutes also receive funding from the government. An example is the Pasteur Institute in France. Because it was impossible to define which part of the biotechnology budgets came from which specific source (government or charity), in this table the total budgets for biotechnology research in these organisations are included.

Iceland	Icelandic Cancer Society	1.67
Switzerland	W.A. de Vigier Foundation, Gebert Rüf Foundation, Foundation Risk Dialogue	4.55
Denmark	Lundbeck Foundation Centres for Neurological Research, Aarhus University Research Foundation, Danish Cancer Society Scientific Committee programme	21.94
Sweden	Swedish Cancer Foundation, Swedish Heart and Lung Foundation, Knut and Alice Wallenberg Foundation	39.87
United Kingdom	Wellcome Trust, Cancer Research UK, British Heart Foundation	811.28
Belgium	National Lottery, Télérive	n.a.
Netherlands	Dutch Cancer Society, Dutch Heart Foundation, Asthma Fund	n.a.
Ireland	Irish Heart Foundation, Irish Cancer Society	6.40
Germany	Foundation for German Science, German Federal Foundation for the Environment	10.75
Norway	Norwegian Cancer Society	4.29
France	Pasteur Institute, Curie Institute, French Association against Muscular Dystrophy	244.18
Italy	Comitato Telethon Fondazione (ONLUS), Italian Association for Research in Cancer (AIRC)	181.12
Luxembourg	AIDS Research Foundation, Foundation for Research in Cancer and Blood Diseases	n.a.
Portugal	Calouste Gulbenkian Foundation	28.78
<b>Total funding of biotechnology by charities</b>		<b>&gt; 1355</b>

Source: BioPolis Research

## 4.7 Conclusions

The data for the public funding of biotechnology show that the EU15+3 countries are doing better than Canada and Asia, but that they are seriously behind the USA. The EU15+3 countries are also doing worse than the rest of the world when corrected for population.

When analysing the public funding for biotechnology in more detail for the individual countries, it appears that funding profiles differ for each country, regardless of their position in the performance cluster. It is therefore very difficult to draw any conclusions on any links between the funding profile and

the performance cluster. Nevertheless, more general conclusions across the performance clusters can be made.

The public funding of biotechnology in the individual EU15+3 countries shows that the larger countries also belong to the larger funders: Germany, France, United Kingdom, Spain and Italy. However, there is a rather large difference in spending between these countries; Germany had the largest budget in 2002-2005 and France followed with 40% less public funds for biotechnology. The other three spent less than a third of the amount spent by Germany on biotechnology. Belgium, the Netherlands, Finland and Austria form the middle group. The lowest budgets were allocated in the four other Nordic countries, Greece, Portugal and Switzerland. Luxembourg and Iceland had the smallest budgets. When absolute numbers are related to population size, a different picture appears. Finland is the leader. Small countries like Austria, Belgium and Ireland spent as much per million capita as Germany and France, the big spenders. The other large countries, United Kingdom, Italy and Spain, but also the Netherlands, Denmark, Iceland and Norway followed the EU15+3 median. The other countries granted lower funding to biotechnology than the median.

Regional funding is important in some countries, although its share is mainly around 10 to 15%. An exception is Belgium where more than 85% of public funding is provided by regional governments. This is mainly due to the very specific government structure in which regional governments are also responsible for research and development policy.

Biotechnology funding accounted for only small share of total public expenditures on R&D in most EU15+3 countries. In Belgium, Ireland and Finland, biotechnology had a relatively large share in total public funding of R&D (about 10%), but the European median was approximately 4%.

The share of the various types of public funding differed enormously among the countries. Non-policy directed funding was the most important contributor in at least half of the countries. In Denmark, Italy, Germany and France 70 to 80% of public funding was allocated through non-policy directed funding. In Luxembourg all funding was non-policy directed. Generic instruments were important sources of biotechnology funding (40% or more) in eight countries and, in Greece, biotechnology was fully funded through a generic instrument. Except for Greece and Portugal, all other countries used biotech-specific instruments. In five countries these provided more funding than the generic instruments.

In the EU15+3 public funding was mainly directed towards supporting and stimulating biotechnology research. In seven countries governments spent 75% or more of the funds on biotechnology research. In five countries research funds were mainly granted to support high level biotechnology research, while industry-oriented and applied research was a priority in six other countries. Knowledge flow and collaboration was a priority in Iceland, but in the other countries this policy goal was much less important. Portugal, Spain and Sweden spent between 20 and 30% of the research budgets on assuring the availability of human resources, but in other countries this policy goal was less important.

Except for Greece, all other countries had instruments dedicated to commercialisation. Commercialisation was a priority in Finland, France, Iceland and Austria. Supporting knowledge flow from acad-

mia to industry received at least 45% of the biotechnology commercialisation budgets, and up to 70% in the Netherlands and Portugal. The adoption of biotechnology for new industrial applications was a priority in Norway and Iceland and also in France and Italy, but received relatively less funding in the other countries. Firm creation was substantially supported in five countries (20 to 40%), but in the other countries this policy goal was of minor importance. More countries, but especially Belgium, Finland and Spain, invested relatively more funds in encouraging businesses investment in R&D. Activities directed towards public acceptance of biotechnology and biosafety issues were supported in 11 countries. In general, their share was less than 5% of the total public funding for biotechnology. In six countries more than 50% of 'Other' research funds was allocated to research into biosafety issues, while in four countries more than 80% was spent on promoting the public acceptance of biotechnology.

In many of the EU15+3 countries, governments invested mainly in Red biotechnology, although in some countries, governments decided to make a different choice. They invested more in Green (Germany, Netherlands, United Kingdom) or White biotechnology (Germany, Iceland) than in Red biotechnology. ELSA issues were supported in several countries, but only received a small amount of funds. Three countries invested relatively large amounts in basic biotechnology. Within the Green biotechnology area, seven countries prioritised plant biotechnology. In six countries, animal biotechnology received substantial funds, while in three countries at least 40% was granted to food research and applications. The focus on funding specific areas of biotechnology was in many cases not related to the focus on specific fields shown by biotechnology publications. Some countries with a strong focus on health biotechnology in their funding, did not demonstrate a stronger focus than other countries on health biotechnology publications. In contrast, some countries with a strong focus on health biotechnology publications had above average funding for other application areas, such as food, plant or industrial biotechnology.

In 11 of the EU15+3 countries, charities are relevant funders of biotechnology research, with a median share of 10% in total public funding. The main charity organisations are cancer societies and heart foundations. Charities are an especially important source of funding for biotechnology in the United Kingdom, where 35% of the total funding is provided by three large charities.

## 5. Performance of European countries in biotechnology

### 5.1 Introduction

One of the main objectives of the BioPolis project is to explore how national policy activities aimed at fostering the development of biotechnology relate to national performance in biotechnology. Accordingly, the assessment of performance of the various countries under consideration is an important element of BioPolis. The performance analysis also explores whether groups or clusters of countries with similar performance can be identified. If so, comparisons within and between such clusters could contribute to elucidating factors that influence performance, and in particular the role of policy in this context.

In this chapter we will first present an overview of general trends in biotechnology performance in the EU25 compared to the USA and Japan (section 5.2). Following this overview a detailed analysis of country performance with respect to creating and sustaining a knowledge base for biotechnology (section 5.3), and with respect to transmission and application of biotechnology know-how for commercial purposes (section 5.4) will be presented. Section 5.5 will focus on the comparison between different countries in order to identify possible clusters. Finally, section 5.6 will summarise conclusions.

The geographic scope of the analysis presented in this chapter is the 15 Old Member States plus Norway, Switzerland and Iceland (EU15+3). A detailed comparative analysis of new Member States is not included in this section for the following reasons: In many cases the indicators used for the performance analysis are not available for new Member States (e. g. firm counts, information on human resources for biotechnology, information on venture capital investment). In other cases the indicator values for new Member States are very low, so that not firm basis for drawing any conclusions would be available. This holds true, for example, for patent applications at the European Patent Office which were used as an indicator for technology development. Since it takes some time to get used to the European and international patenting procedures, it is quite understandable that new Member States still are not that active at the European Patent Office compared to old Member States. In general, the historical and institutional conditions for developing biotechnology in new Member States are so different from old Member States that comparisons between the two groups of countries would be misleading. Rather, it is more interesting to elaborate on comparisons between new Member States. Due to these peculiarities, we will provide an integral presentation of new Member States and accession countries in Chapter 8 including configuration of policy-making, funding of biotechnology and performance in biotechnology.

As already observed in the preceding Epohite project (Reiss et al. 2004) there is a surprising lack of systematic internationally comparable data on the performance of various national or sectoral biotechnology innovation systems. Since the Epohite project to our knowledge no such systematic and timely analyses have been published. A number of researchers dealt with some specific issues of performance in biotechnology. Frenken et al. (2005) investigated the impact of research collabora-

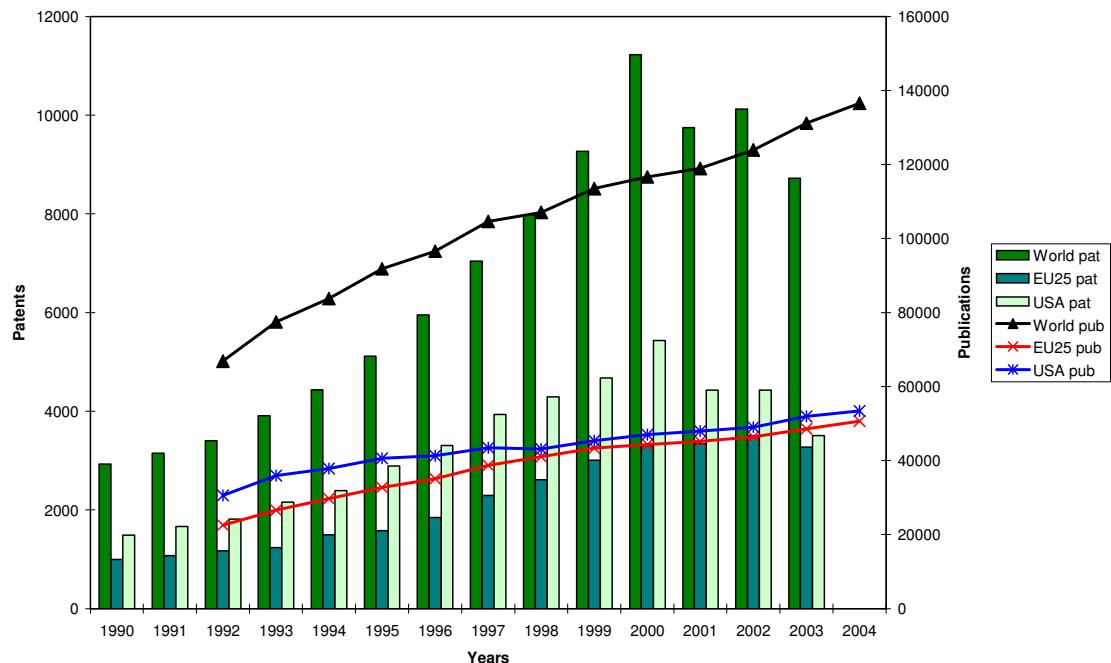
tions in biotechnology and applied microbiology as measured by scientific citations. The authors provide evidence that the diffusion of scientific knowledge as measured by citation rates is influenced by both, intra- and inter-organisational characteristics. In another analysis Thorsteinsdottir et al. (2006) explored the potentials and characteristics of health biotechnology in developing countries based on an analysis of health biotechnology publications in these nations. They show a significant growth in health biotechnology applications in developing countries, which is larger than the growth in industrialised countries. However, the visibility of such research is still limited. The analysis also points out the significance of international cooperation. Two other groups employed publication analyses for measuring outcomes of public funding of biotechnology-related research. Mendis and McLean (2006) observed a relation between funding volume and publication output in health and medical research in Australia. Druss and Marcus (2005) investigated publication outcomes of National Institutes of Health grants in the USA. They could show the visibility and potential utility of efforts to study the link between grant funding and research findings. Sapsalis et al. (2006) provide an investigation on the value of patents in biotechnology. Among others they conclude that there is a need to stimulate star scientists to codify their tacit knowledge into valuable patents. In another piece of work using patent indicator Saviotti et al. (2003) provide an analysis of knowledge dynamics and the mergers of firms in biotechnology. Finally, Gittelman (2006) presents a comparative study of the performance of the biotechnology industry in the USA and France based among others on patent analyses.

This brief literature survey indicates that the present performance analysis of the BioPolis project fills an important gap in the publicly available performance literature related to biotechnology innovation systems.

## **5.2 Overview - general trends in publication and patenting activities**

In order to obtain an overview of the long-term development of scientific and technological performance, the scientific output in terms of publication counts and the technological performance in terms of patent counts were analysed world-wide, for EU25 and for the USA (Figure 5.1). Publication intensity was measured for the period 1992 to 2004. During this period we observe a continuous growth of publication output in all regions. On a word level the absolute number of publications more than doubled within twelve years. The publication intensities in EU25 and in the USA developed rather similarly since 1992. A slightly higher number of biotechnology publications originated from the United States. However, the gap of publication output between the USA and Europe has become smaller if we compare the period 1992 to 1997 with the most recent years.

Figure 5.1 Long-term trends in publications and patent applications in biotechnology



Source: BioPolis Research

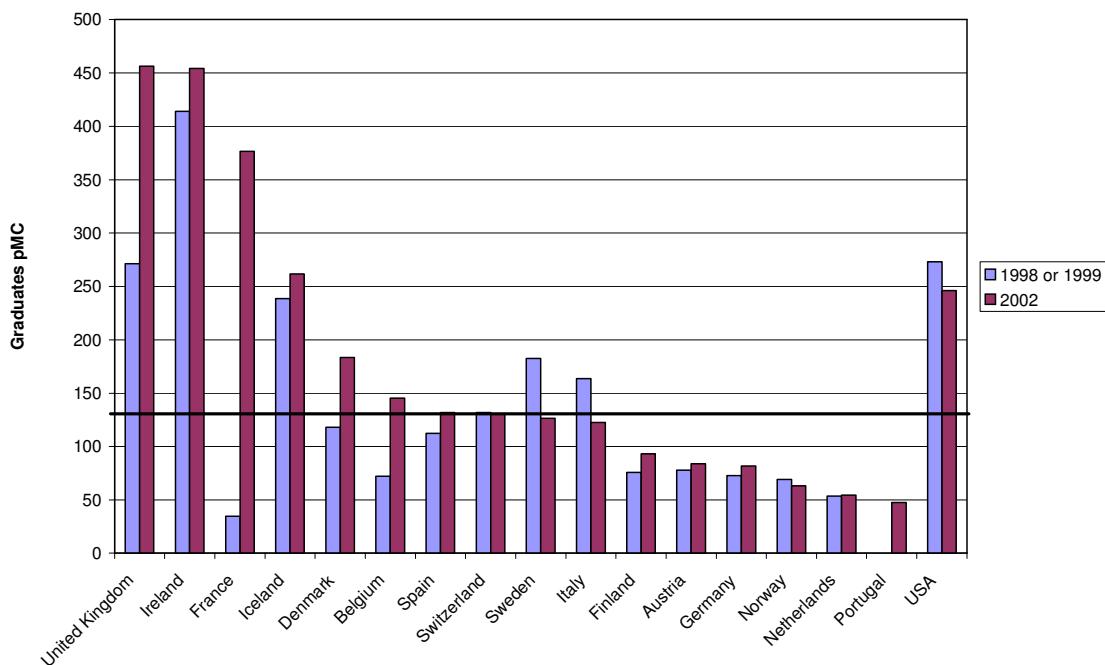
World-wide patenting activities indicating the extent of technological development with relevance for biotechnology increased almost four-fold between 1990 and 2000. However, since 2001 we observe a decline in world-wide biotechnology patenting. This decreasing trend is shaped by patenting activities in the United States. European patenting activity seems to be less affected by the general downturn trend. The decreasing patenting propensity in biotechnology which is mainly observed in the United States most likely is due to the stock market problems of high-tech sectors which became dramatic in 2001. Obviously, inventing activities as indicated by patent applications are much more sensitive to such negative (or positive) external factors than scientific activities as indicated by publication output. The counteracting trends of patenting activities in the United States and Europe since 2000 also resulted in a levelling out of differences between the two regions. In 2003 almost similar numbers of patent applications are observed from Europe and the United States while in the preceding years a clear lead of the United States could be detected.

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

An important prerequisite for developing and sustaining the national knowledge base in biotechnology is the availability of highly qualified personnel. As a proxy for measuring this effect the number of PhD graduates related to the size of a country was used. Unfortunately, the OECD statistics providing such information does not use an own biotechnology classification. Rather, respective data is only available for life sciences as a whole, such overestimating the effect for biotechnology. Figure 5.2 indicates pronounced differences between European countries with respect to the number of PhD graduates

per million capita per year. The United Kingdom, Ireland and France are countries with the highest rate of graduates, while Finland, Austria, Germany, Norway, the Netherlands and Portugal are well below the European average (as measured by the median of the countries considered).

Figure 5.2 Number of graduates in life sciences per Million Capita (pMC)



The line indicates the European median in 2002

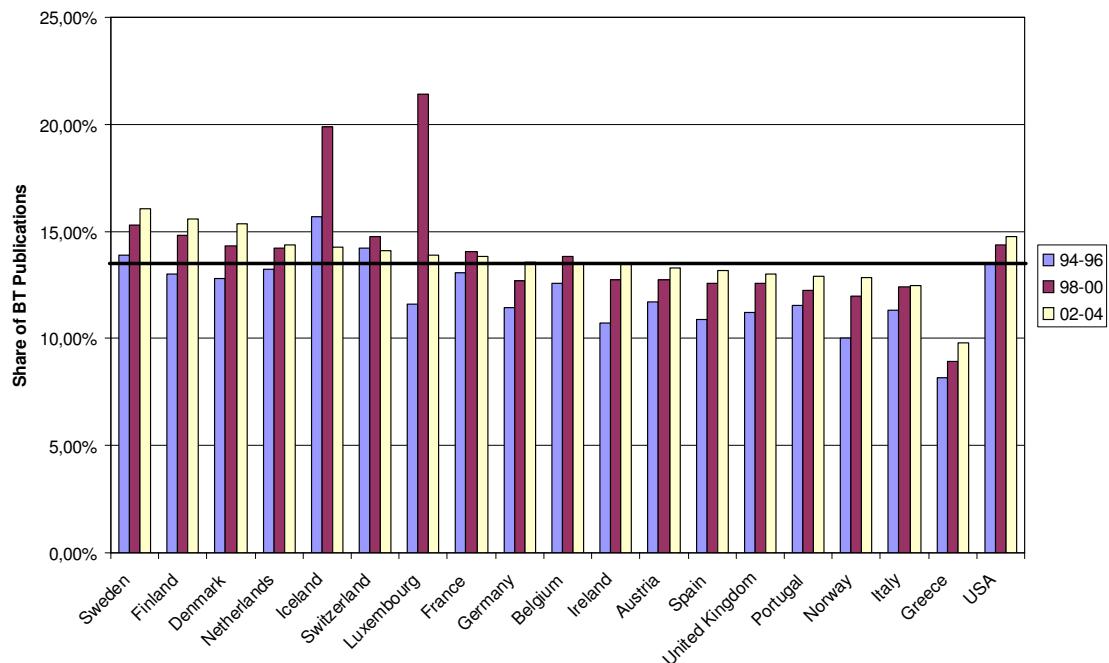
Source: BioPolis Research

Comparing different time periods in some countries remarkable increases in the human resource indicator can be observed. This is in particular the case for France, Belgium, Denmark and the United Kingdom. In the case of France the enormous difference between the two periods might also be due to different statistical delineations and therefore should be taken with caution. Interestingly in some countries we also observe decreases in the output of graduates as, for example, in the case of Sweden and Italy. The respective indicator for the United States for 2002 (246 graduates pMC) is at a level between Denmark and Iceland. In 1998 we observe a higher indicator value in the United States comparable to the United Kingdom. It seems that the number of graduates in life sciences in the United States has decreased between the two periods considered.

Due to different national settings, historical developments and strategies, the significance of biotechnology could be different in the various European countries. In order to assess the significance of biotechnology, the share of biotechnology publications in all publications of a country was calculated. The results presented in Figure 5.3 firstly indicate that the share of biotechnology publications in all publications is rather similar in all European countries in the most recent period, ranging roughly between 10 and 15 %. The European average (median) in 2002-2004 is around 13 %. Obviously, the

focus on biotechnology at least as measured by scientific output is rather similar for all European countries.

Figure 5.3 Share of biotechnology publications in total publications



The line indicates the European median in the period 2002-2004

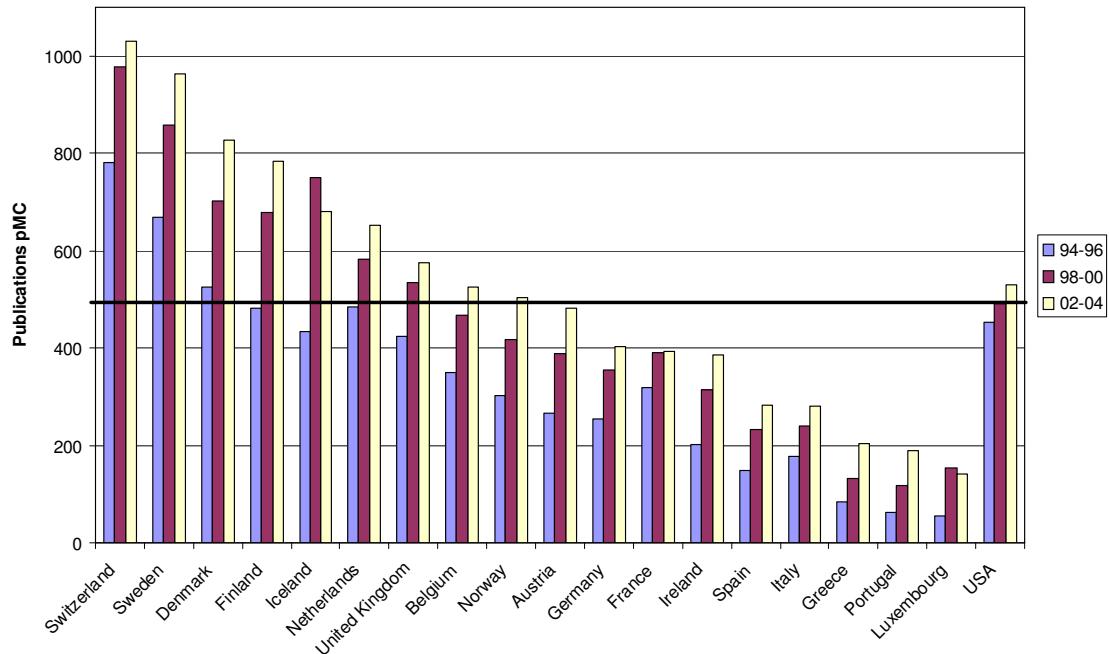
Source: BioPolis Research

Further, in almost all countries we observe increasing significance of biotechnology between 1994 and 2004. For comparison, the share of biotechnology publications in total publications in the United States is slightly higher than the European average starting from 13 % in 1994-1996 and increasing to about 15 % in 2002-2004, indicating a slightly stronger focus on biotechnology in the United States.

In addition to these general trends there are also some interesting differences by country. Biotechnology seems to gain more importance in smaller high-performing (see following sections) countries, such as Sweden, Finland, Denmark, Iceland or Switzerland. In most of the Southern countries the significance of biotechnology is below the European average. In some countries such as Iceland, Switzerland, Luxembourg, France and Belgium we observe a slightly decreasing significance of biotechnology. The rather strong effects observed for Luxembourg and Iceland might be due to small absolute values.

Figure 5.4 presents the relative scientific output in biotechnology of European countries as measured by publications per Million Capita. Switzerland and the Nordic Countries (Sweden, Denmark, Finland, Sweden and Iceland) perform best according to this measure and also show the highest relative growth rates of publication output in biotechnology.

Figure 5.4 Relative biotechnology publication activities as measured by the number of biotechnology publications per Million Capita (pMC)



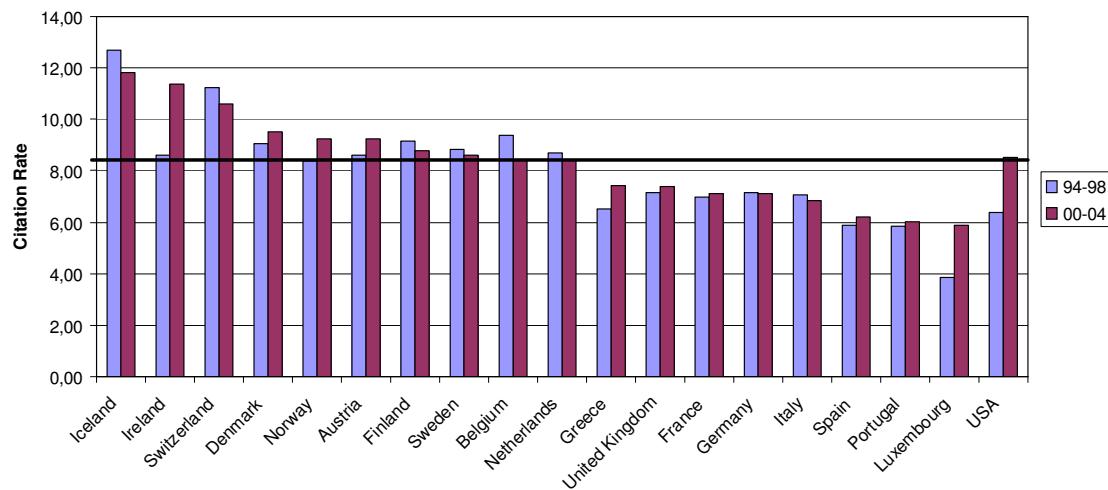
The line indicates the European median in the period 2002-2004

Source: BioPolis Research

Looking at the large European countries (Germany, France, United Kingdom) the United Kingdom is the best performing one with a relative scientific output in the most recent period above European average. France and Germany on the other hand, are performing below the European average. Remarkably in the case of France there seems to be stagnation in scientific output between 1998 and 2004, while most other countries express a clear growth. The Southern countries and Luxembourg rank at the end of the performance scale. In the case of the United States we observe a publication output of 529 publications pMC in 2002-2004, placing the United States between Belgium and the United Kingdom and also above the European average. In addition, publication output increased continuously in the United States over all three periods.

The analysis of the number of citations to biotechnology publications (Figure 5.5) which was used as an impact measure reveals that the scientific impact is highest in smaller countries, such as Iceland, Ireland, Switzerland, Denmark, Norway, Austria or Finland.

Figure 5.5 Citations to biotechnology publications



The line indicates the European median in the period 2002-2004

Source: BioPolis Research

The larger countries such as the United Kingdom, France, Germany and Italy, are performing at a similar level which, however, is below the median value of the countries considered. These data lead to the conclusion that there seems to be a "small-country" bias. Small countries show a relatively large citation rate. We propose the following explanation: In terms of number of publications usually large countries have a larger "middle quality" share of research results (in terms of impacts), leading to a "dilution" of papers with outstanding impact from these countries in a large number of medium-impact publications, while smaller countries have usually "low in the number, but good in quality" publications. This could be explained by a certain concentration of resources in small countries towards selected research groups. In other words, small countries may concentrate their resources in outstanding research units, which would lead to the effect that a lower number of publications may have greater impact.<sup>21</sup> Considering the different time periods analysed there seems to be no general performance trend.

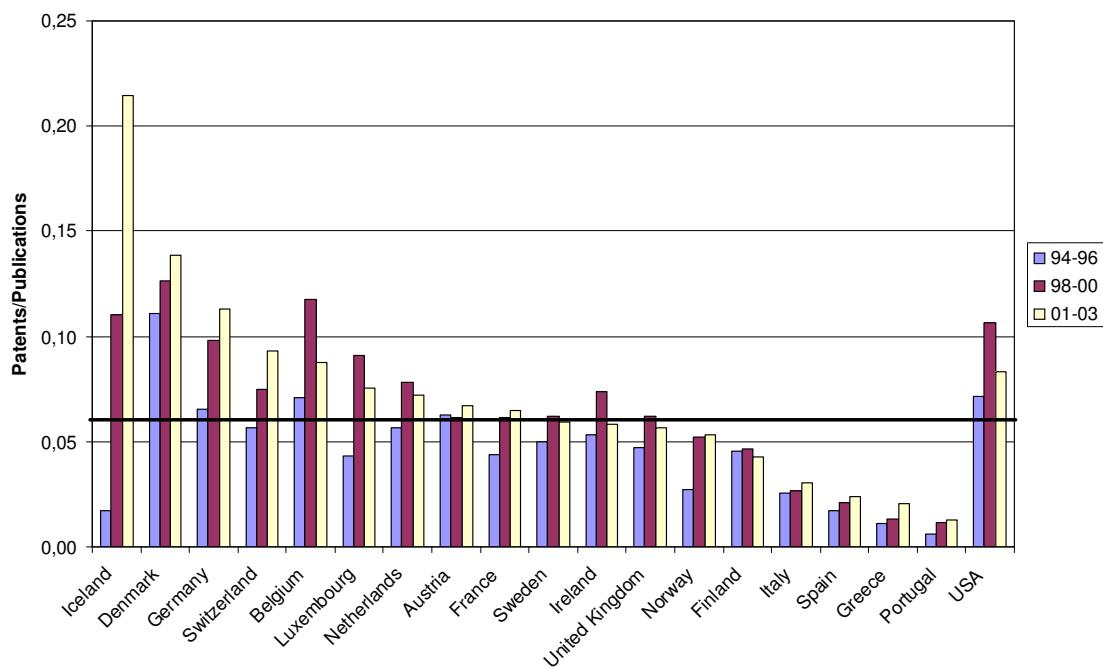
For comparison, the citation rates of the United States were 8.54 in 2000-2004 and 6.39 in 1994-1998, placing the United States at the level of Sweden for the most recent period. Considering the above discussion of the small-countries effect, the difference between the United States and the larger European countries in terms of publication impact seems to be even larger as indicated by the mere indicator values.

<sup>21</sup> It should be noted, however, that two smaller countries, Portugal and Luxembourg, do not comply with this "small-country rule". Further, we did not explore this "small-country" bias in detail during the BioPolis project. Additional research would be required to confirm this explanation.

## 5.4 Performance of European countries in commercialising biotechnology

In order to obtain a general impression of the commercial orientation<sup>22</sup> of European countries in biotechnology, we related the patent output as a measure for technology generation and commercial interest to the scientific publications output, which could be considered as a measure for scientific activities. Hence, a high patent-publication ratio provides a rough indication of a rather strong commercial orientation. The respective data as presented in Figure 5.6 indicate a broad variety of the degree of commercial orientation among European countries. Iceland, Denmark, Germany and to a lesser extent Switzerland, Belgium, Luxembourg and the Netherlands reveal a rather strong commercial focus, while in particular the Mediterranean countries but also Finland and Norway seem to put less emphasis on commercial orientation during the most recent period. All other countries exhibit a rather balanced commercialisation/scientific activities ratio around the median value of the countries considered. The United States, for example, are comparable with the Netherlands in this respect. In some countries the patents/publications ratio changed considerably over the 10-years period examined. In this context, the strong growth in Iceland should be interpreted with some caution due to low absolute figures.

Figure 5.6 Share of patent applications over publications in biotechnology



The line indicates the European median in the period 2001-2003.

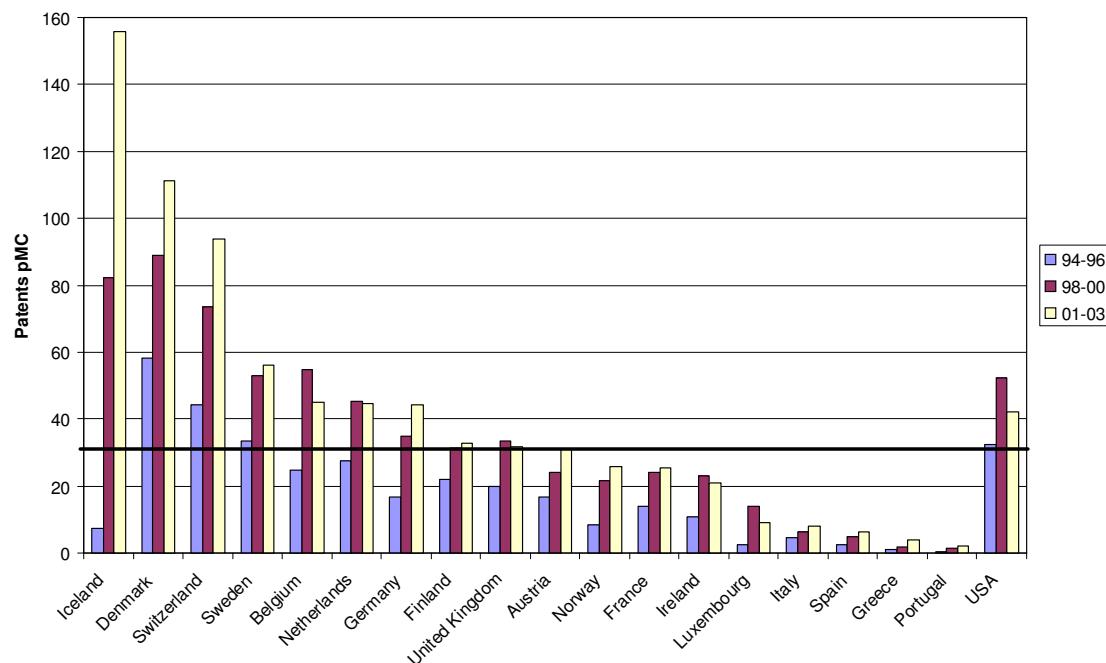
Source: BioPolis Research

<sup>22</sup> Data for constructing commercialisation indicators in terms of biotechnology products on the market or processes used in production is not available via publicly accessible statistics or databases. Instead, within BioPolis we used a set of other indicators providing indirect evidence on the status of commercial applications of biotechnology.

Denmark, Switzerland and in particular Germany present a continuous growth of this indicator. Other countries such as Belgium, the Netherlands, Ireland or the United Kingdom had a peak in commercial orientation in the medium period 1998 to 2000 which might reflect to some extent the high-tech boom during that period. A similar observation is made for the United States having a clear peak in this medium period.

Performance in terms of technology generation as measured by patent applications on a per-capita basis also reveals a broad variety among European countries (Figure 5.7). Top performing countries in the most recent period are Iceland, Denmark and Switzerland. At the end of the performance scale the Mediterranean countries and Luxembourg can be found. Most countries improved across all time periods considered. Exceptional growth rates are observed for Iceland, Denmark and Switzerland. Also Germany was able to catch up, while Belgium and the Netherlands lost ground towards the most recent period. For comparison the trend in the technology generation as measured by patent applications on a per-capita basis in the United States indicates a rather high value in the medium period 1998 to 2000 (52) where the United States is positioned at a sixth place just behind Sweden on the performance scale. However, towards the most recent period patenting activities decreased in the United States reaching a similar level as the Netherlands and Germany (see section 5.2).

Figure 5.7 Biotechnology patent applications per Million Capita (pMC)



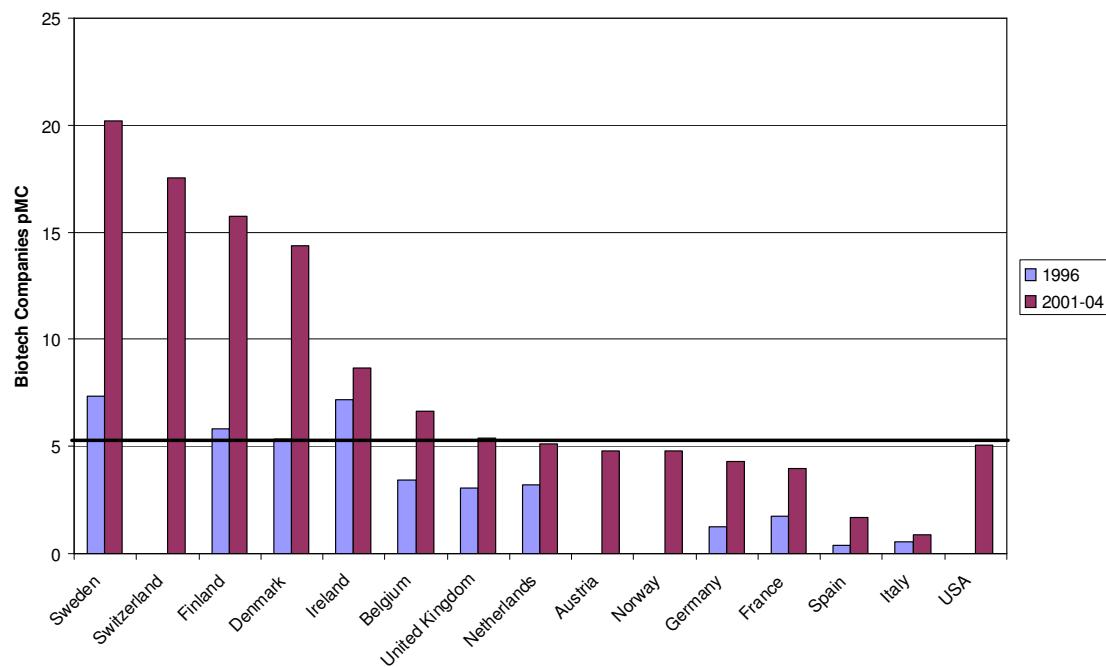
The line indicates the European median in the period 2001-2003

Source: BioPolis Research

The biotechnology industry in the countries considered has grown substantially during the last ten years. This is indicated at least in those countries where data was available for the number of biotech companies in the mid 90s and in the most recent period of time (Figure 5.8). Remarkably, also the performance of large countries such as Germany, France and the United Kingdom improved signifi-

cantly. Strongest growth rates among all countries are observed in Sweden, Denmark and Germany. Mediterranean countries perform rather weakly in terms of development of their biotech industry. The number of biotech companies should be considered as a rough indicator for commercial performance since it suffers from inconsistent definitions of "biotech company" and also does not contain any qualitative information such as size or commercial viability of a company. The number of biotechnology companies per Million Capita in the United States during the period 2001 to 2004 is close to the European median value, indicating that at least in terms of company counts there is no difference between Europe and the United States.

Figure 5.8 Development of the biotechnology industry in Europe as indicated by the number of biotechnology companies per Million Capita (pMC)



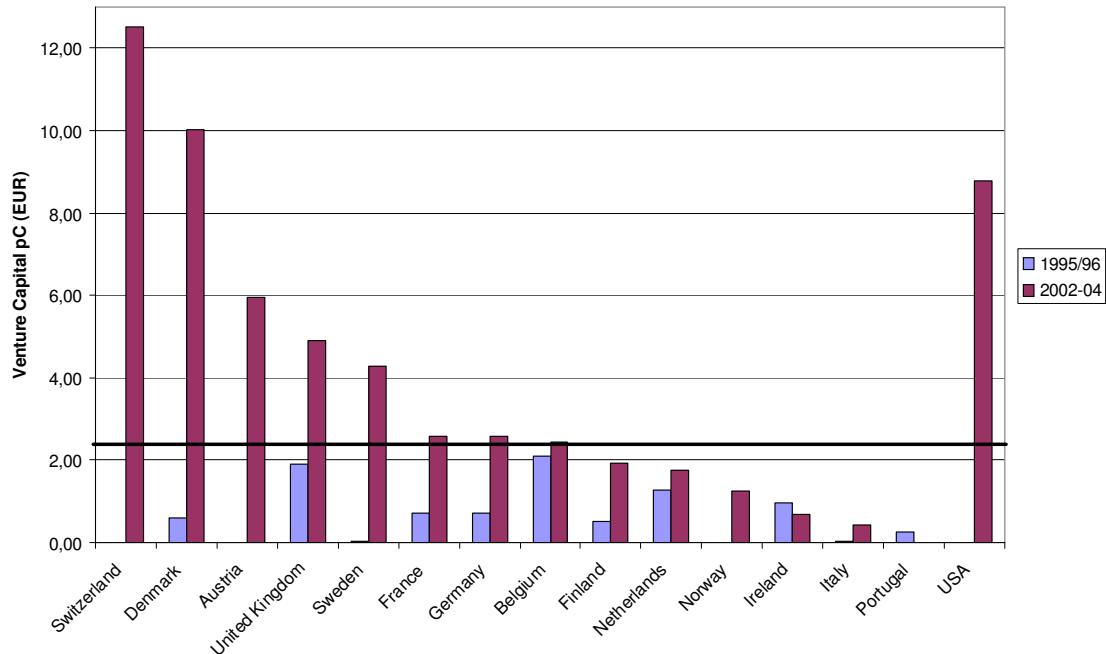
The line indicates the European median in the period 2001-2004

Source: BioPolis Research

Measuring commercialisation of biotechnology in terms of venture capital investment reveals an increasing flow of venture capital into almost all countries considered since the mid 1990s (Figure 5.9). The smaller countries Switzerland, Denmark, Austria and in addition the United Kingdom and Sweden attracted the highest venture capital flow between 2002 and 2004. France, Germany, Belgium and Finland have been performing at a medium level. All Mediterranean countries (as far as data availability allows conclusions) obviously were not attractive locations for venture capital investment during the periods considered. In some countries we observe a considerable growth in venture capital investment, starting from a low level (Denmark, Sweden, France and Germany). A different situation can be observed for the United Kingdom where already in the mid 1990s large amounts of venture capital have been invested into biotechnology, and in addition investments more than doubled since that

time. Belgium and the Netherlands are other countries, where venture capital was already important in the mid 1990s. However, growth rates have been moderate since that time.

Figure 5.9 Investment of venture capital in biotechnology in European countries related to the size of the population



The line indicates the European median value for the period 2002-2004.

Source: EVCA 2006

In the previous Epohite project (Reiss et al. 2004) venture capital investments into biotechnology have also been analysed for the period 1999-2000 at least for some countries. During that period the stock markets experienced a hype situation in Europe, and the financial climate was very favourable for high-tech firms. Comparison with the Epohite data allows for some countries to monitor how venture capital investments were influenced by the development of the stock market with the boom period in 2000 and its breakdown in the following years. Interestingly, for most countries where data is available (Denmark, Austria, United Kingdom, Sweden and Finland), we observe a continuous growth over all three periods (1995-1996, 1999-2000, 2002-2004). On the other hand, in France and Germany venture capital investment reacted very sensitive to the stock market development, in a sense that investments in the most recent period are still below the investments in 1999-2000. This could be interpreted as an indication for a rather unstable investment situation for biotechnology in these countries at the threshold of this century.

## 5.5 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 which allow calculating a composite indicator for each performance type. The

index indicators were developed using a scaling system which transfers the score of each indicator to a 100-point scale with 100 points representing the sum of the indicator values of all countries<sup>23</sup>. For comparison, the median value of the 100-point scores is calculated.

Table 5.1 Index values of knowledge base indicators used for performance clustering

	BT publications pMC	Citations per BT publication	Average knowledge base indicator
	2002-2004	2000-2004	2000-2004
Austria	5,17	6,15	5,66
Belgium	5,65	5,62	5,64
Denmark	8,89	6,34	7,62
Finland	8,43	5,86	7,14
France	4,22	4,74	4,48
Germany	4,33	4,73	4,53
Greece	2,19	4,95	3,57
Iceland	7,32	7,89	7,61
Ireland	4,15	7,59	5,87
Italy	3,03	4,56	3,79
Luxembourg	1,52	3,92	2,72
Netherlands	7,01	5,62	6,31
Norway	5,40	6,16	5,78
Portugal	2,03	4,01	3,02
Spain	3,04	4,14	3,59
Sweden	10,37	5,72	8,05
Switzerland	11,07	7,06	9,06
United Kingdom	6,18	4,93	5,55
		<i>European median</i>	5,65

Source: BioPolis Research

It should be noted that composite indicators ought to be used with care since the composite scores can vary considerably, depending on the composition process (see e. g. Grupp 2007). Accordingly in the following we will also present the individual scores used for the composition process and include them in the discussion.

Table 5.1 and Table 5.2 summarise the index values for both indicator types - knowledge base indicators and commercialisation indicators. In the last column of each table the composite indicator for each performance type is presented. The last row of each table contains, for comparison, the European median value calculated on the basis of the included European countries.

23 This procedure was also applied to the average indicator presented in the last columns of Table 5.1 and Table 5.2. Accordingly, there is a slight difference between the index average and the calculated average.

Table 5.2 Index values of commercialisation indicators used for performance clustering

	BT patents pMC	BT firms pMC	Venture capital pMC	Average commercialisa- tion indicator
	2001-2003	2001-2004	2002-2004	2001-2004
Austria	4,14	4,04	11,00	5,53
Belgium	5,99	5,85	4,68	4,76
Denmark	14,88	12,64	19,83	13,65
Finland	4,39	13,80	4,24	6,47
France	3,39	3,50	5,09	3,46
Germany	5,90	3,78	5,01	4,24
Greece	0,51	n.a.	n.a.	0,44
Iceland	20,86	n.a.	n.a.	18,05
Ireland	2,80	7,61	1,16	3,34
Italy	1,08	0,77	0,88	0,79
Luxembourg	1,19	n.a.	n.a.	1,03
Netherlands	5,96	4,49	3,55	4,04
Norway	3,47	4,20	2,56	2,95
Portugal	0,28	n.a.	n.a.	0,24
Spain	0,85	1,43	n.a.	0,99
Sweden	7,50	17,74	8,49	9,72
Switzerland	12,53	15,39	24,00	14,97
United Kingdom	4,25	4,73	9,49	5,32
			European median	4,14

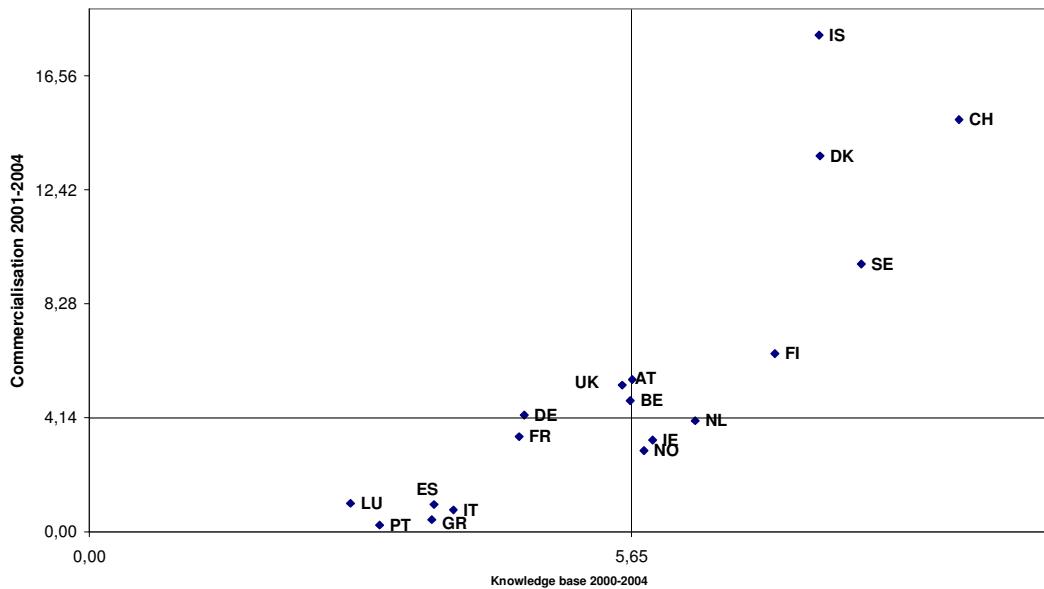
n.a.: no data available

Source: BioPolis Research

In the case of commercialisation indicators (Table 5.2) for some countries (Greece, Iceland, Luxembourg, Portugal and Spain) not all three commercialisation indicators could be calculated due to lacking data. Accordingly, interpretation of the composite indicators for these countries should be taken with care.

With respect to the composite indicator, countries can be differentiated into those scoring above the European median and those scoring below the median value. In order to explore the relation between knowledge-based performance and commercialisation performance, the two composite indicators were represented graphically in a two-dimensional graph (Figure 5.10). This analysis seems to indicate a linear relationship between performance of the knowledge base and performance in terms of commercialisation for the countries considered.

Figure 5.10 Combined performance clustering of European Member States based on performance with respect to the knowledge base and with respect to commercialisation during the period 2000-2004



The lines in the graph represent the median values for each performance type.

Source: BioPolis Research

In order to test this hypothesis, a multivariate least squares analysis based on optimising weights of the individual indicators (Table 5.1 and Table 5.2) was performed based on a simulation study using the pairs-bootstrap approach according to Freedman (1981). The results of this analysis clearly confirm the above observation. In particular, we find a significant positive relationship between the publication indicator and the firms indicator: The higher the publication activity, the higher the number of firms in a country. We conclude from this analysis that indeed commercial and scientific performance are closely interrelated in a positive way.

In addition, the positioning of the various countries in this two-dimensional performance space allows identifying groups of countries with similar performance. There is a group of countries performing above the European median with respect to both performance measures. Neglecting Iceland due to limited data availability (see above), these countries include Switzerland, Denmark, Sweden and Finland. Another group of countries comprised of the United Kingdom, Austria, Belgium, the Netherlands, Ireland, Norway, Germany and France are performing roughly at a similar level as the European median with respect to both performance types. A third group of countries (Italy, Greece, Spain, Portugal and Luxembourg) is performing clearly below the European values with respect to both types of performance. It should be noted that with the exception of Italy all countries in this cluster are characterised only through a limited number of commercialisation indicators (see Table 5.2).

For detecting dynamic changes in the performance positioning of the various countries a comparison with the results of the Epohite project (Reiss et al. 2004, Table 4) could be made. Due to limited data

availability, not exactly the same indicators for computing the commercialisation and the knowledge base scores could be used in Epohite and in BioPolis, so that stringent comparisons are not feasible. However, some rough trends can be observed.<sup>24</sup> Comparing the two periods 1999/2000 (Epohite) and 2000/2004 (BioPolis) reveals that most countries did not change their performance positioning over this period of about three years. Within the top-performing quadrant this includes in particular Denmark, Sweden and Finland, within the low-performing quadrant Italy, Spain, Portugal and Greece (and to a lesser extent also France) did not change their position. Other countries such as Germany, the United Kingdom, Belgium and the Netherlands also seem to be more or less stable. However, they are at least with respect to one performance measure very close to the respective median value, so that it seems difficult to state clear changes for these countries. In summary, the stability of positioning seems to indicate that most of the high-performing countries could maintain favourable conditions for the performance of their national biotechnology innovation systems, while on the other hand most of the countries performing below the median values did not succeed to improve the situation.

In addition to the stable countries we observe remarkable changes for a few countries. This includes in particular Austria and Ireland. Compared to 1999/2000 Austria maintained a strong knowledge base in the most recent period, but in addition it succeeded in pushing its commercial performance above the European median. Ireland on the other hand, improved its knowledge base and is still performing below the median value in terms of commercialisation performance. If we compare the performance of Ireland between three periods (1995/96, 1999/2000 based on Epohite (Reiss et al. 2004); 2000-2004 based on BioPolis), we observe an interesting pattern: Ireland started from high commercial and low knowledge base performance in the mid 1990s, dropped to low performance in both categories in 1999/2000 and now moved to high knowledge base/low commercialisation performance in the latest period. Considering the strong relationship between both performance categories (see above) we would expect Ireland to move up to the high performance cluster with respect to both categories in the future if policy conditions keep being favourable for supporting the maintenance and development of Ireland's knowledge base *and* commercialisation.

In order to check whether the results of this positioning are influenced by exceptional performance just in one indicator category, a comparison of Figure 5.10 and Table 5.1 and Table 5.2 is necessary. In addition, we performed a sensitivity analysis identifying the lower and the upper boundaries of the two composite indicators. The results of this analysis are presented in Figure 5.11 and indicate that the positioning of the individual countries is rather robust.

The qualitative analysis of the influence of individual indicators on the positioning results reveal the following: In the case of the best-performing cluster, the scores for Switzerland and Denmark seem to be rather robust since all individual indicators for both knowledge base and commercialisation performance, are scoring high. In the case of Sweden, the two indicators publications per Million Capita

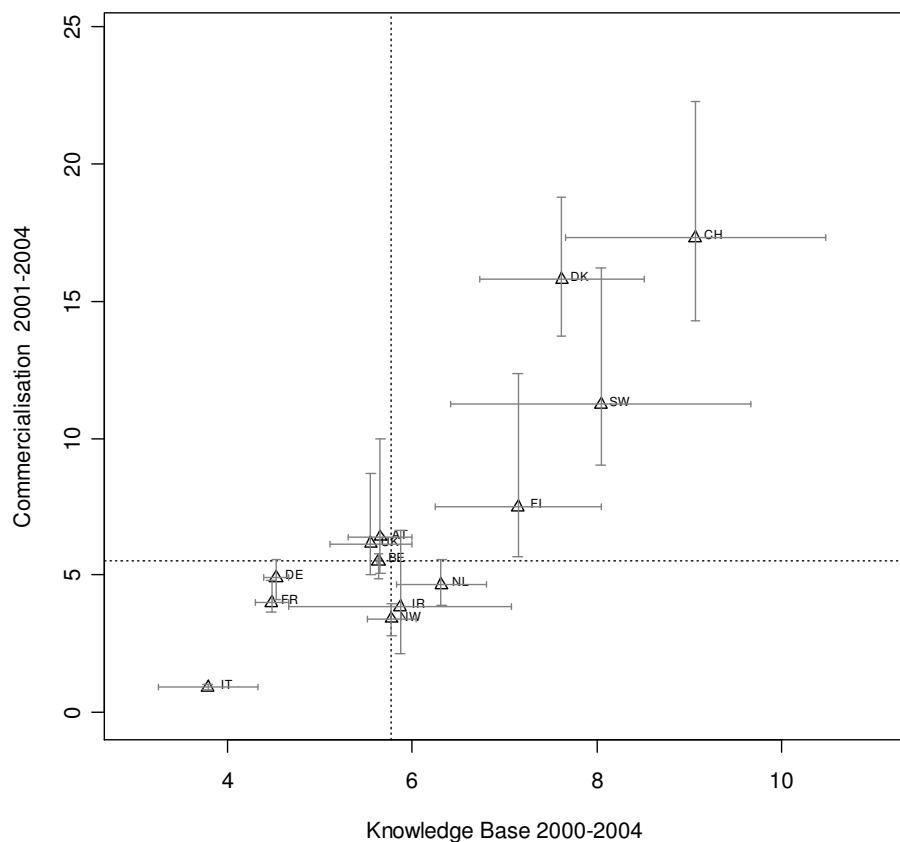
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<sup>24</sup> Switzerland, Iceland, Luxembourg and Norway were not covered by the Epohite project and will not be included in the following discussion.

and number of biotech firms per Million Capita seem to push the composite indicators to higher scores. In the case of Finland we observe a similar effect again for the biotech firms indicator.

In the case of the median performing group of countries, for the United Kingdom, Belgium and Norway all individual indicators are rather homogeneous. In the case of all other countries the overall results are influenced to some extent by the scores of one individual indicator. For Austria the commercial performance is pushed to high scores by a rather high venture capital indicator. According to expert information the high score of the venture capital indicator is due to very few individual investments in Austria which were singular events. Accordingly, the position of Austria with respect to commercial performance seems to be overestimated just looking at the composite indicator. For the Netherlands again the venture capital indicator seems to influence the overall result disproportionately to the negative direction. Accordingly, the commercial performance of the Netherlands might be a bit underestimated. France presents a similar case as Austria with a rather strong positive effect of the venture capital indicator.

Figure 5.11 Sensitivity analysis of the performance clustering of European Member States as presented in Figure 5.10



Source: BioPolis Research

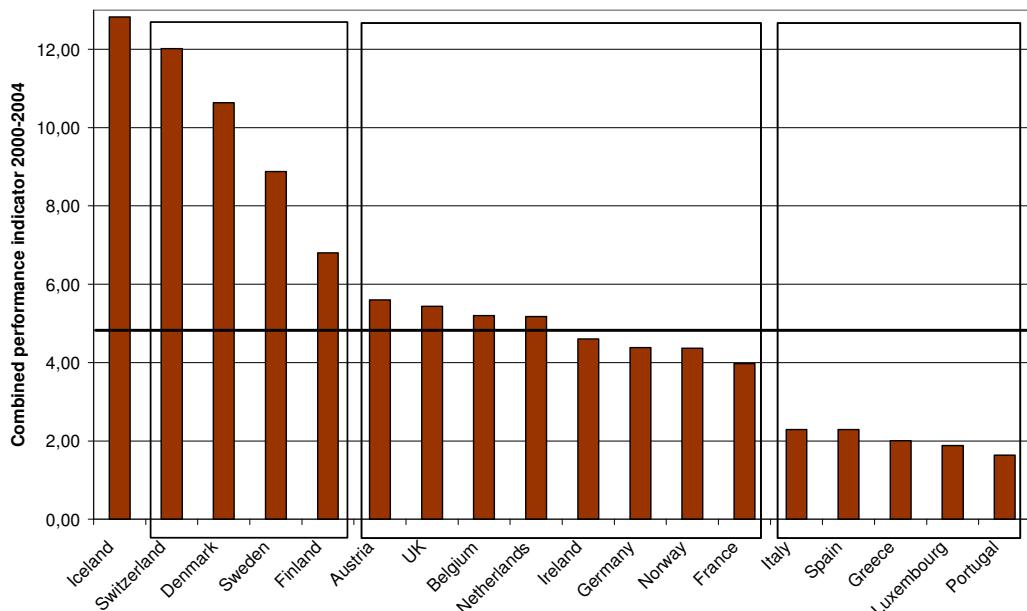
In the case of Germany the good commercial performance is mainly due to high scores of the patenting indicator, and in the case of Ireland the biotechnology firms indicator is pushing performance to positive scores.

Looking at the low-performing cluster a discussion based on individual indicators is meaningful only for Italy due to lacking data in all other cases. There seems to be no above-average effect of any individual indicator in this case.

In order to obtain additional evidence of possible similarly performing groups of countries, a cluster analysis according to the Ward-Linkage method using SPSS and based on the individual indicators for commercial and scientific performance was carried out. This analysis also identifies the best-performing cluster made of Switzerland, Denmark, Finland and Sweden. In addition, it recognises Iceland as a special case confirming the above discussion. Within cluster 2 the cluster analysis identifies a closer relationship between Belgium, the Netherlands and Norway on the one hand, and Germany and France on the other hand.

Taking into account the limitations of composite indicators as discussed above and the influence of individual indicators on the composite indicator result, the presented country clustering should be interpreted with some caution. Nevertheless, it provides a good starting point for a discussion of possible policy effects on country performance in biotechnology based on similar performance scores. Figure 5.12 summarises the overall clustering by combining the two composite indicators into one performance indicator.

Figure 5.12 Combined performance ranking adding index knowledge base and commercialisation indicators



Source: BioPolis Research

## 5.6 Summary and conclusions

There is still a lack of systematic performance analyses of biotechnology. BioPolis fills an important gap in this literature by providing systematic, comparative, timely performance data.

With respect to the scientific performance we observe in all European countries a similar focus on biotechnology in terms of publication output. Obviously within the scientific universe of the countries considered, biotechnology-related research is playing a comparable role. In the case of the United States we find a slightly stronger focus on biotechnology. Measuring the knowledge base performance in terms of publication output and publication impact identifies the smaller European countries, such as Switzerland, Sweden, Denmark or Finland as the best-performing ones. All in all, we find rather strong differences in the performance of the countries considered. Accordingly analysing and discussing a combined European performance index is less meaningful. The best-performing European countries achieve higher performance scores than the United States. Within the whole spectrum of European countries considered the United States would be positioned in the first half. Thus, our analysis does not provide evidence for a clearly leading role of the United States in terms of scientific performance in biotechnology.

The analysis of the commercial orientation of the various countries in biotechnology as measured by the publications/patents ratio identifies a broad range of scores. Some countries, such as Iceland, Denmark, Germany, Switzerland or Belgium seem to put much stronger emphasis on commercialisation, or speaking more generally on technology generation out of biotechnology research than other countries, such as Italy, Spain, Greece or Portugal. The measurement of commercial performance using the three indicators patent applications, number of biotechnology firms and amount of venture capital invested into biotechnology also identifies a rather broad range of differently performing countries. As in the case of scientific performance again the smaller countries - Denmark, Switzerland, Sweden, Belgium, and with respect to some indicators also the Netherlands - are performing best. At the end of the performance scale we find the Mediterranean countries. The comparison with the United States reveals a similar situation as in the case of scientific performance. The best European countries are clearly ahead the United States. The USA would be positioned in the first-performing half of the countries considered. The comparison of scientific performance and commercialisation performance of the individual countries yields one of the most interesting results of this analysis. We find clear evidence for a positive correlation between scientific and commercial performance.

The combination of the two performance measures (scientific and commercial) also allows identifying three clusters of differently performing countries. We could identify a group of countries performing above the European median with respect to both performance measures. These include Switzerland, Denmark, Sweden and Finland. Another group of countries comprised of the United Kingdom, Austria, Belgium, the Netherlands, Ireland, Norway, Germany and France is performing roughly at a similar level as the European median with respect to both performance types. Finally, a third group of countries - Italy, Greece, Spain, Portugal and Luxembourg - is performing clearly below the European median.

## 6. Dynamics of Biotechnology Policy-Making in Old Member States

### 6.1 Introduction

This chapter reviews changes to biotechnology policy-making since the period 1994-98, in the 15 Member States of the EU25 at that time, as well as in Iceland, Norway and Switzerland (EU15+3). Information about biotechnology policy-making for the period 1994-1998 is contained in the national reports prepared for the Inventory project (Enzing et al. 1999). This is compared with the situation shown in the national reports produced for the BioPolis project.

Biotechnology has been identified as a priority by many European governments because it is considered one of the key technologies that will contribute to economic performance in the 21<sup>st</sup> century. The policy trends discussed in this chapter are consonant with those that Biegelbauer and Borrás (2003) suggest mark a transition from technology to innovation policy. On the one hand there is a growing understanding by governments of the systemic nature of the innovation process that demands the need to coordinate research policy with other national policies such as economic, agricultural, health and regional policies. On the other hand, innovation also requires an expansion of the knowledge base and the fostering of networks between the knowledge base and firms as well as between firms.

This chapter considers how far governments are meeting these demands by discussing trends in two important characteristics of policy-making that affect the biotechnology innovation system. Section 6.2 focuses mainly on changes to policy-makers and policy coordination, as well as changes to the research funding actors and research performers. Section 6.3 presents developments in the amount of funds allocated to biotechnology and in the relative importance of biotechnology in national R&D and policy making. Section 6.4 analyses developments in the policy profiles of the countries under consideration. In section 6.5 the specialisation patterns within Europe are addressed and how these have changed in the period between 1994-1998 and 2002-2005. The future dynamics of national biotechnology policy making in the Old Member States are addressed in section 6.6. Finally, the last section (6.7) draws conclusions on the dynamics of biotechnology policy making in Europe.

### 6.2 Changes in national biotechnology research systems

There have been changes to the actors involved in forming policy in the biotechnology innovation system in several countries, both at the national and regional level. At the national level, the motive for change is to focus on supporting innovation, often by improving overall coordination between policy for public research and technological development and policy for innovation. This is necessary because the majority of countries have numerous ministries involved in supporting research and its application. The usual pattern is for one ministry to be responsible for higher education and research

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25 Excluding Luxembourg, as it is not covered by previous research.

and another for promoting innovation, industrial research, technology transfer and support to small firms. In addition, ministries responsible for agriculture, health and the environment often support biotechnology research in their own institutes. The situation is even more complex in countries like Belgium, France, Germany, Spain and Switzerland where responsibilities for science, technology and innovation can be shared with regional governments. Policy fragmentation has been recognised as a problem in several countries, including Austria, Belgium, Portugal and Spain<sup>26</sup> and this problem persists.

### **6.2.1 Growing role of regional governments**

The strongest trend apparent in the 17 European countries is the rise in regional government participation in biotechnology policy-making. In the period 1994-98 significant regional policy-making for biotechnology was concentrated in Member States where the regions have responsibility for supporting university research and economic development (Germany, Belgium and Spain). Some regions in Norway and the UK also played a limited role in research and technology development policy (RTD), as part of responsibilities delegated from National Government. By 2002-2005 all these countries were playing a much more active role in developing and operating a wide range of new RTD policy instruments, both generic and biotech-specific. In addition, regions in Austria, France, Italy and Switzerland have become involved in biotech policy-making; they tend to focus their efforts on research commercialisation and support to SMEs. Regional involvement in Italy commenced in 2001, when the regions were given power to intervene in the formulation of RTD policies. This has led to the development of regional innovation plans that take local conditions into account. In several Member States, including Italy, policy instruments are funded jointly by central government and the region. In addition, Denmark's Regional Research and Innovation Action Plan (started in 2004) aims to develop regional innovation systems.

The range of activities covered by regional policy instruments is extremely broad. They include grants for public sector research, and establishing Centres of Excellence at one end of the spectrum, to support for research commercialisation at the other. Instruments for biotech commercialisation include setting up incubators and science parks, providing risky equity investment, upgrading the technological capabilities of SMEs, and grants for industrial research. A central aim, common to many regions' policies, is to support biotech cluster development, through strengthening the science base together with the encouragement of networking and links between all those involved in biotech research within a region.

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<sup>26</sup> Spain had a single Ministry for Science and Technology from 2000-2004 but this was abolished in 2004 with the change of government

## 6.2.2 Transnational clusters

The 1994-98 period saw the emergence of transnational cluster development, for instance the Medicon Valley Academy cluster in southern Sweden and Copenhagen and the BioValley biotech cluster, located between Alsace in France, northwest Switzerland and South-Baden in Germany. This trend has strengthened with the formation of other transnational clusters, such as the MedCoast Scandinavia cluster (Norway and Sweden) formed in 2000 and Scanbalt BioRegion, which links 11 countries: Denmark, Estonia, Finland, Germany, Iceland, Latvia, Lithuania, Norway, Poland, Russia and Sweden. Its aims include the coordination of joint efforts in research, technology transfer, innovation and economic development as well as promoting collaboration between academia, hospitals, industry and public authorities. Similar efforts are now appearing in the south of the EU with the inauguration in 2005 of EuroBioCluster South which links Spain, France, Switzerland, Italy and South Germany and involves a consortium of regional authorities, cities and universities (Louet 2005). In 2006, it was joined by the Transalpine BioCluster, involving France, Italy and Switzerland.

## 6.2.3 Policy coordination

The approaches adopted to improve policy coordination and support innovation differ by country, reflecting existing national and regional arrangements, and no overall trend is apparent. The following examples demonstrate this diversity of approach. Denmark created a new Ministry of Science and Technology in 2001 to centralise responsibilities for ensuring coordination between all government research funding; previously many Ministries were involved in science and technology policy and there was thought to be a problem "in assuring basic research in areas of relevance for applied research" (Assouline, 1999). It is supported by a new Research Coordination Committee which has responsibility to ensure coordination between all government research funding. In the Netherlands the ministries involved in biotechnology policy-making meet regularly in the Interdepartementaal Overleg Biotechnologie; there is also an attempt for generic innovation policy to be complemented by sector-specific innovation policy. A new Austrian institution, the Austrian Council for Research and Technology Development was created in 2000 to improve overall policy coordination. Similar attempts to improve policy coordination are ongoing: Austria is seeking to improve vertical coordination between its federal and regional levels. In 2006, the UK's Department of Trade and Industry merged its Innovation Group with its Office of Science and Technology to form the new Office of Science and Innovation. The aim is to achieve more effective coordination between science and innovation.

One of the reasons for restructuring research funding agencies during the past few years has been to improve coordination, as in France, Iceland, Switzerland and Sweden. Iceland has merged the previously separate Science and the Technical Funds, to end the previous demarcation in funding between basic and applied research. In Switzerland the funding agencies for innovation and basic research have intensified cooperation; increasingly, funding instruments are jointly designed and developed. Similarly, the 2000 reorganisation of the Sweden research council structure aimed to promote collaboration between research and development. Perhaps the most radical change has occurred in France, which has decentralised R&D policy-making. There has been an increase in the number of actors

involved and a shift from a hierarchical structure towards a more networked one. In the new, decentralised system national organisations make decisions at the regional level in cooperation with regional governments. Some current initiatives by funding agencies also focus on improving coordination. Austria is attempting to reduce the fragmentation in funding instruments and the Brussels region of Belgium intends to do more to cluster life sciences initiatives.

Coordination has also been evident in the restructuring of agencies involved in offering funds and other types of commercialisation support to the business sector. In Norway, Innovation Norway was formed in 2003 by merging several existing organisations into a unitary agency to promote industrial development. Germany merged two state-owned banks and another bank that had programmes to support innovation in SMEs to form a new Bank Group. The Group set up an SME Bank offering services to SMEs from a single point. In 2004, Austria created the Austrian Research Promotion Agency, by merging four formerly independent agencies, including the Industrial Research Promotion Fund and the Bureau for Innovation and Technology. Similarly, in France a new organisation, OSEO *anvar*, was created to support firms by the merger of ANVAR, the agency that gave grants to enterprises to support the commercialisation of research, with CDC Entreprises, the agency that provided support to firms in need of capital for R&D activities.<sup>27</sup>

#### **6.2.4 New research funding agencies**

In two countries – France and Ireland - new research funding organisations have been established with the aim of correcting weaknesses in the research system. In 2005, the National Research Agency was created in France. It allocates funds to both basic and applied research by response mode and could mark part of a slow transition from a French research system based on block grants for public research organisations towards one that is more integrated, competitive, and better linked to industry's needs.

In Ireland several new research organisations have been created to meet the aim of creating a highly innovative, knowledge-based economy and reverse the former situation where only a very small proportion of funds supported basic research. Supporting these new research organisations involved a doubling of government expenditure on R&D between 1993 and 2003. The four new Irish research funding organisations all allocate grants on a competitive base, and are:

- Science Foundation Ireland, funded in 2000, supports policy-directed basic research in strategic priority areas: ICT and life sciences.
- Programme for Research in Third Level Institutions of the Higher Education Authority, set up in 1998, supports the implementation of strategic planning by universities and institutes of technology with capital grants to improve buildings, equipment and infrastructure and recurrent grants for research programmes, graduate output and conditions for interdisciplinary research.

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<sup>27</sup> CDC Entreprises was a subsidiary of the state-dominated Development Bank for Small and Medium Enterprises.

- Irish Research Council for Science, Engineering and Technology, founded in 2000, funds non-policy directed, basic research.
- Irish Research Council for Humanities and Social Sciences, founded in 2001, also funds non-policy directed, basic research.

### 6.2.5 New research performers

The establishment of new research organisations was rather rare in the period 2002-2005. What was common, however, was the formation of centres of research, some of them virtual centres that integrated research groups and facilities on one or more university campuses; some centres also involved companies. Some examples include the Walloon Government which used EC Structural Funds to set up GIGA, an interdisciplinary research centre in applied genoproteomics. It was created by integrating various research groups and research facilities in bioinformatics, genomics, proteomics, transcriptomics, transgenics, and protein production at the University of Liege with laboratories and offices for biomedical businesses, and a biotechnology training centre for continuing education. The National Platform for Systems Biology in Denmark integrates three research groups at different universities. The Netherlands Genome Initiative has funded five Centres of Excellence comprising consortia of universities, research institutes and companies for various aspects of genomics (including one on the ethical, legal and social aspects), two Genomics Technology Centres providing national equipment and services in bioinformatics and proteomics technologies, four Innovative Clusters focussing on applied research for industry and a number of research programs. It is sometimes difficult to distinguish these apparently semi-permanent research organisations from intra and inter-organisational collaborative research arrangements that are promoted by research initiatives or programmes. Such initiatives are discussed in detail in Section 6.3.3 below.

However, some countries have created new biotech research organisations. Norway has created the Norwegian University of Life Sciences in Ås. In Italy, a new Institute of Technology was established in Genoa as a centre of excellence focusing on three technological platforms: one of the platforms is nanobiotechnology. The Irish Agriculture and Food Development Agency, which conducts research in its own Institutes, received government funds to improve its infrastructure and invested in building two new Biotechnology Centres during the period 2002-2005: one focuses on food biotechnology and the other on plant biotechnology. Finally, there are also plans for the two Federal science institutes in Belgium to set up a joint molecular laboratory in 2007. Previously, no Federal institutes focused on biotech research.

Table 6.1 presents an overview of new research facilities and “centres”. The majority of new research facilities and integrated centres focus on research in new areas of biotechnology such as systems biology or genomics and proteomics. The new Irish laboratories, however, are the result of a decision in 2000 by the TEAGASC, the Agricultural and Food Research Agency, to develop capability in biotechnology in its research institutes.

Table 6.1 New Research Facilities and Integrated Centres

Country	New Research Organisation	New Integrated Centre & Field of Research
Denmark		National Platform for Systems Biology
Austria	Institute for Medical Genome Research and Systems Biology	
Belgium	Molecular Biology Lab (2007)	GIGA: interdisciplinary Centre of Applied Genoproteomics
Denmark		National Platform for Systems Biology
Ireland	National Plant Biotechnology Research Centre; Moorepark Biotechnology Centre at the Moorepark Food Centre	
Italy	Institute of Technology, Genoa (nanobiotechnology)	
The Netherlands		5 Centres of Excellence in various aspects of genomics; 2 Genomics Technology Centres in bioinformation and proteomics 4 Innovative Cluster in ecogenomics, nutrigenomics, celiac diseases and virus genomics
Ireland	National Plant Biotechnology Research Centre; Moorepark Biotechnology Centre at the Moorepark Food Centre	
Norway	Norwegian University of Life Sciences	2 Centres of Excellence: Molecular Biology and Neuroscience; and the Aquaculture Protein Centre
Italy	Institute of Technology, Genoa (nanobiotechnology)	
UK		4 interdisciplinary research centres for social science research on the impact of genomics

Source: BioPolis Research

## 6.3 Changes in importance of biotechnology in governmental policies

### 6.3.1 Growth in funding of biotechnology

The funds for biotech research for EU15+3 (minus Luxembourg) have grown considerably over the period between 1994-1998 and 2002-2005: from an annual average of 2 076M ECU to 3 063M EUR (Table 6.2). The non-policy-directed funding for biotech research rose by 69.1% during this period. The budget allocated to biotech research through biotech specific instruments increased by 11.9%

and through generic instruments by 39.1%. On average, expenditure on commercialisation activities constitutes 13.8% of the average annual budget in 2002-2005. Comparison of funding of commercialisation activities in the two periods is not possible because commercialisation was not fully addressed in the Inventory study. In some countries these policy instruments were included, some of them were linked to research (e.g. the activities of BioResearch Ireland, the UK's LINK programme or the BioRegio competition in Germany), but such coverage was not comprehensive. For the period 1994-1998 the budgets for commercialisation are included in the budget under 'Research'. We have the impression, however, that there is now increased funding for such activities.

The proportion of non-policy directed and policy directed funding in the total hardly changed since 1994-1998. In 1994-1998, the distribution between non-policy directed, biotech specific and generic instruments was: 56.0% - 30.7% - 13.3% and in 2002-2005: 55.3% - 28.3% - 16.4%.

Table 6.2 Average annual spending on biotech research and commercialization through non-policy directed and policy directed instruments, EU15+3 (excl. Luxembourg), in the periods 1994-1998 and 2002-2005

	Research				Commercialisation		
	NPD	PD-Biotech specific	PD-Generic	Total	PD-Biotech specific	PD-Generic	Total
1994-1998 (in M ECU)*	1 162	638	276	2 076	- **	-	-
2002-2005 (in M EUR)	1 965	714	384	3 063	292	201	493

\* The annual budget for period 1994-1998 is corrected for inflation according to the harmonised index of consumer prices of 1996 (2005=100) (EUROSTAT)

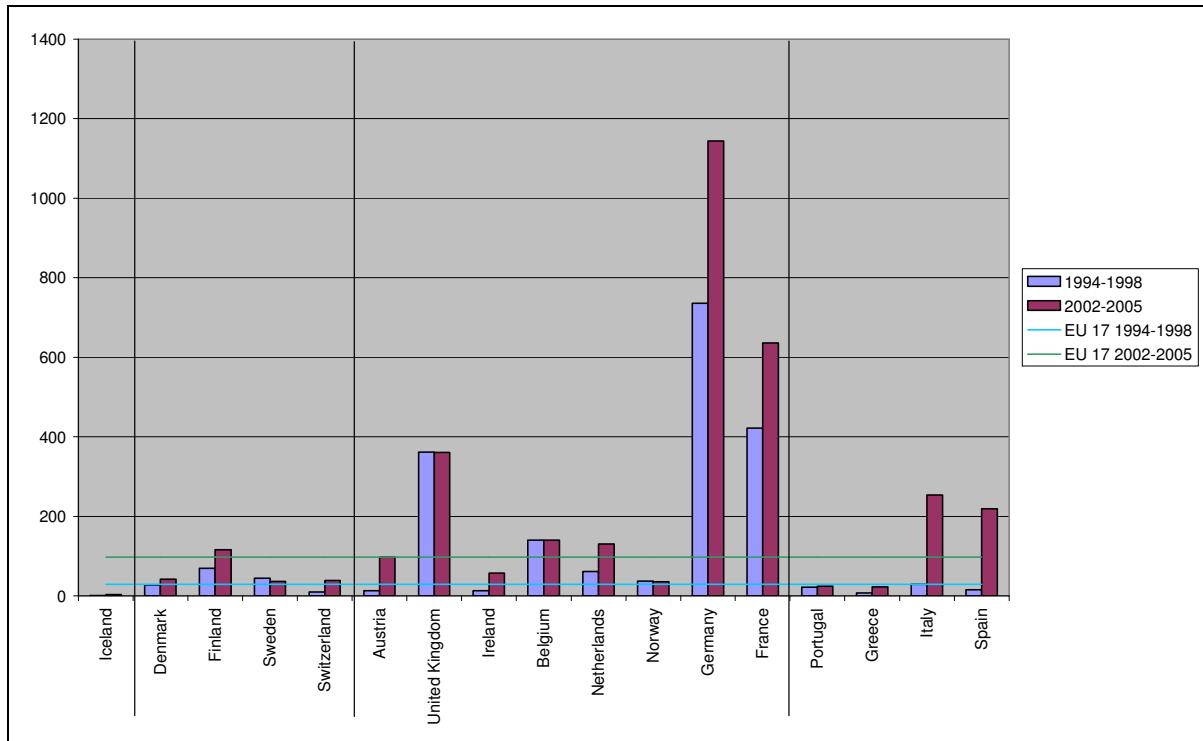
\*\* Funding of commercialisation activities was not specifically addressed in the Inventory and was included in the budget under 'Research'

Source: Enzing et al. 1999 (data for 1994-1998), BioPolis Research

Table 6.2 excludes data for the period 2002-2005 for the third category 'Others'. This covers funding for Biosafety with an average annual budget of 71.2M EUR and ethical, legal and social aspects (ELSA) activities with an average annual budget of 9.2 M EUR.

Figure 6.1 shows changes to the annual budget for biotech activities through policy directed instruments since 1994. In several countries the growth in funds for biotech has been relatively large, with funds at least doubling in Austria, Greece, Italy, Ireland, the Netherlands, Spain and Switzerland. Spain and Italy, in particular, showed a very large increase. Funds for biotech decreased in Sweden and Norway and stayed more or less on the same level in Belgium, Portugal and the UK.

Figure 6.1 Average annual budgets for biotechnology in the periods 1994-1998 and 2002-2005



\* The annual budget for the period 1994-1998 is corrected for inflation according to the harmonised index of consumer prices of 1996 (2005=100) (EUROSTAT)

Source: BioPolis Research

### 6.3.2 Relative importance of biotech in national R&D and innovation policies

In order to draw conclusions about changes in the importance of biotechnology in national R&D and innovation policies, we have calculated the share of biotech expenditures in total governments' expenditure on R&D, for two years: 1998 to represent the period 1994-1998 and 2003 to represent the period 2002-2005.

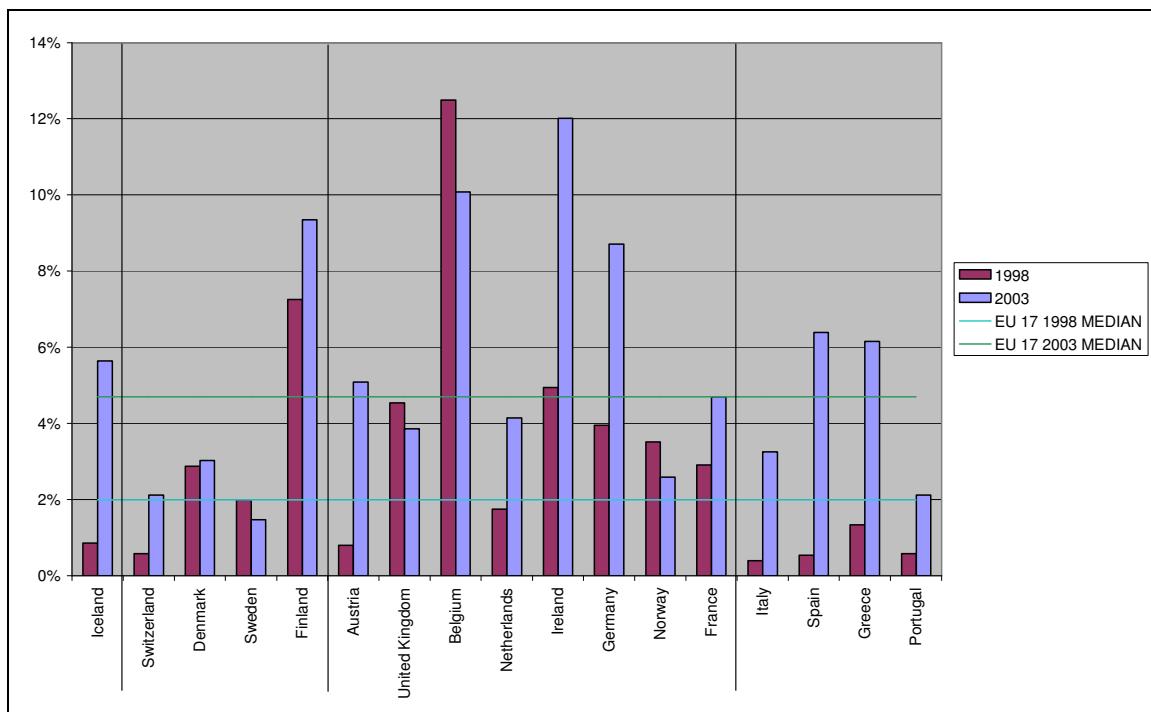
Figure 6.2 shows that in all countries in Cluster 1, except for Sweden, the relative importance of biotech funding in governmental budgets has increased. In other words, the national public R&D budgets for biotechnology have grown faster than the overall public budgets for R&D, which might imply that biotechnology has gained a higher priority in national R&D and innovation policy making. In Finland, which already had a high figure in 1994-1998 (about 7%), the share of funding for biotechnology has risen to 10%. Moreover, its figures are above the average of the 17 countries for both periods.

In addition, almost all countries in Cluster 2 show an increase; only Belgium, Norway and the UK show a decrease in the share of biotech R&D in total government R&D expenditures. In the period 1994-1998, Belgium had the highest share (13%), which dropped to 10% in 2002-2005; this is still far above the average of the 17 countries for that period. The dramatic increase of biotech R&D funding in Austria and Ireland is especially interesting, as the overall performance in biotechnology of both

countries also improved considerably since 1999/2000 (Reiss et al. 2003). At that time, both countries belonged to the group of countries (together with France) that performed below the median. BioPolis performance data show that Austria is the best performing country in Cluster 2 and Ireland has moved from the bottom of Cluster 3 in 1999/2000 (which is comparable to the bottom of Cluster 2 in BioPolis) to fifth position, above Germany, Norway and France. One could assume that poor performance figures for 1999/2000 may have been an impetus for national policy makers in these countries to invest heavily in biotechnology.

All countries of Cluster 3 show an increase in relative funding of biotech R&D as a share of total government R&D expenditure; in particular Spain's increase for the period 2002-2005 was above the median increase of the EU17.

Figure 6.2 Share of biotech R&D funding as % of the governmental expenditures on R&D for EU15+3 (minus Luxembourg), in 1998 and 2003



\* For Greece, Iceland, Norway, Sweden, GOV ERD data for 1997 (instead of 1998) have been used; for Italy and Sweden GOV ERD data for 2004 (instead of 2003) have been used

Sources: Eurostat, BioPolis Research

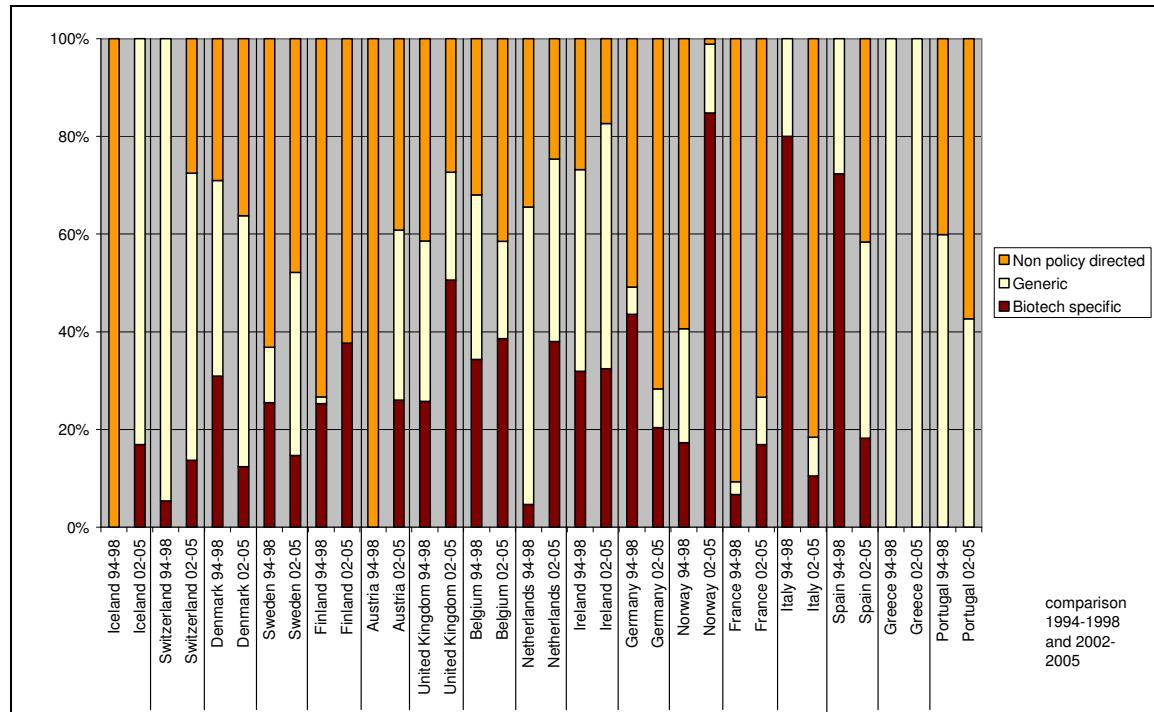
## 6.4 Changes in biotech policy profiles in the period 1994-1998 and 2002-2005

The national biotechnology policy profiles are composed of several elements. For the analysis of dynamics in national biotechnology policies two main elements will be addressed: funding and the policy goals that are addressed through policy-directed instruments.

### 6.4.1 Funding profiles

Figure 6.3 shows the composition of the funds that have been spent on biotechnology through non-policy-directed and policy-directed instruments in the period 1994-1998 (Inventory data) and the period covered by BioPolis: 2002-2005.

Figure 6.3 Share of non-policy directed and generic and biotech-specific (both policy-directed) funding of biotechnology for the periods 1994-1998 and 2002-2005



Sources: Enzing et al. 1999 and BioPolis Research

It should be mentioned that data collection in BioPolis was more systematic and also more structured than the Inventory data. For instance, for a number of countries (including Spain and Italy) no data on non-policy directed funding or regional funding was collected for the period 1994-1998.

Figure 6.3 shows that in the more than ten years period between 1994 and 2005, the national funding profiles of biotechnology have changed considerably. In seven countries (Austria, Belgium, Finland, France, Iceland, Netherlands, Norway, Switzerland and the UK) the relative contribution of funding for biotechnology through biotech specific instruments has increased. In these countries, there is relatively more funding of biotech through biotech specific instruments than through generic instruments for the period 2002-2005 than in the period 1994-1998. In five other countries (Denmark, Germany, Italy, Spain and Sweden) the trend is reversed, with generic funding of biotechnology increasing at the expense of biotech specific funds. In Iceland and Austria the funding part of the policy profile changed completely. In the period 1994-1998, biotechnology (and all other research) was funded only through non-policy directed instruments. In the period 2002-2005 biotech specific and generic policy instruments had been introduced.

There is no consistent pattern of change to the funding profiles of the group of countries within each cluster. In some countries in Cluster 1 funding through biotechnology specific instruments has taken a more prominent place (Finland, Switzerland), and in others it was just the other way around (Denmark, Sweden). Cluster 2 is similar; five countries have switched towards more biotech specific funding (Belgium, France, Norway, The Netherlands and the UK) and two towards more generic funding (Germany and Ireland). The funding part of the policy profiles of Greece and Portugal hardly changed; the profile of the two other countries in Cluster 3 (Italy and Spain) switched away from biotech specific towards more generic funding.

#### **6.4.2 Goals and instruments profiles**

Table 6.3 presents the policy profile for 2002-2005 in terms of the coverage of policy goals by generic and biotech specific instruments; changes with the profile of 1994-1998 are also indicated. The comparative analysis shows one important trend: in ten of the 17 countries (Austria, France, Germany, Norway, Iceland, Italy, Netherlands, Spain, Switzerland and the UK) national and regional governments have introduced new biotech specific instruments to attain policy goals that were not formerly covered by these instruments.

The trend is least visible in the countries of Cluster 1, where none of the countries, except Switzerland, introduced new biotech specific programmes to cover new policy goals since 1994-98. For Finland and Sweden the profile analysis does not show any significant changes since 1994, although new programmes have been introduced that have replaced others (see also 'New research priorities'). In Denmark the Danish National Advanced Technology Foundation and the Danish Council for Strategic Research both introduced new generic instruments to support basic and applied interdisciplinary research within nanotechnology, biotechnology, IT and communications technology (policy goal 3). One of them also covers ELSA activities (policy goal 8). The biotech specific instrument that addressed ELSA activities in Denmark during the period 1994-1998 was no longer in place.

Switzerland showed most changes to its policy profile as new biotechnology specific instruments were introduced to stimulate industrial R&D, the adoption of biotechnology by industry and ELSA activities. However, these new instruments deal with rather very small programmes and the changes compared to the 1994-1998 period also reflect the different methods of collecting data between Inventory (1994-1998) and BioPolis as in BioPolis the promotion activities of the cantons – mainly biotechnology clusters – are now included, but were not included in the Inventory.

The trend of creating more biotech specific policy instruments to support biotechnology growth was most visible in the countries of Cluster 2. Except for Belgium, where the profile did not change, and Ireland that has introduced only new generic instruments during the last ten years, the other five countries have created a larger number of new biotechnology instruments (in some cases in combination with new generic instruments) to foster biotechnology development.

Table 6.3 Coverage of policy goals by policy directed instruments for the support of biotechnology for the period 2002-2005 and changes since 1994-1998

Countries	Policy goals								
	9. To encourage business investment in R&D	8. To monitor and improve the social acceptance of biotechnology	7. To assist firm creation	6. To stimulate the adoption of biotechnology for new industrial applications	5. To facilitate transmission of knowledge from academia to industry	4. To assure availability of human resources	3. To support knowledge flow and collaboration among scientific disciplines	2. To promote high level of industry-oriented (and applied) research	1. To promote high level biotechnology basic research
Iceland	[-]/-	G*/B**	G/B	-/-	G/B	G/B	G/B	-/-	G/B
<i>Cluster 1</i>									
Switzerland	G/[-]	G/B	G/B	G/[-]	G/B	-/B	G/B	-/B	G/B
Denmark	G/B	G/B	<b>G</b> /-	-/-	G/-	G/-	NA	<b>G</b> /[-]	G/-
Sweden	G/B	G/B	G/B	G/B	G/B	G/B	G/-	G/-	G/B
Finland	G/B	G/B	-/B	-/B	-/B	-/B	-/B	-/B	-/B
<i>Cluster 2</i>									
Austria	<b>G</b> /B	<b>G</b> /B	<b>G</b> /-	<b>G</b> /B	<b>G</b> /B	<b>G</b> /B	<b>G</b> /B	<b>G</b> /B	<b>G</b> /-
UK	G/B	G/B	G/B	<b>G</b> /B	G/B	G/B	G/B	-/B	G/B
Belgium	G/B	G/B	G/B	-/B	G/B	-/-	G/B	-/B	G/B
Netherlands	G/B	G/B	-/B	-/-	G/B	-/-	-/B	-/B	-/-
Ireland	G/B	G/B	<b>G</b> /B	<b>G</b> /B	G/B	G/B	<b>G</b> /-	<b>G</b> /-	<b>G</b> /-
Germany	G/B	G/B	<b>G</b> /B	<b>G</b> /B	G/B	<b>G</b> /B	G/B	-/B	<b>G</b> /B
Norway	G/B	G/B	<b>G</b> /B	<b>G</b> /B	[-]/B	<b>G</b> /B	-/-	-/B	G/B
France	G/B	G/B	G/B	G/-	G/B	G/B	<b>G</b> /B	-/-	G/B
<i>Cluster 3</i>									
Italy	G/B	G/B	<b>G</b> /B	<b>G</b> /B	G/B	G/B	<b>G</b> /B	-/B	<b>G</b> /B

Spain	G/B	G/B	G/ <b>B</b>	G/ <b>B</b>	G/B	-/ <b>B</b>	G/B	-/-	G/ <b>B</b>
Greece	<b>G</b> /-	G/-	<b>G</b> /-	-/-	G/-	<b>G</b> /-	-/-	-/-	G/-
Portugal	G/-	G/-	-/-	<b>G</b> /-	G/-	<b>G</b> /-	-/-	-/-	G/-

\* G-coverage by generic instruments; B-coverage by biotech specific instruments

\*\* Change since 1994-1998: bold = new type of instrument introduced since 1994-1998; [-] = instrument(s) are no longer in place; **G** or **B** = not know whether this policy goal was covered in 1994-98

NA: no data available

Source: BioPolis Research

In particular, the profile of Austria has changed a lot as biotechnology was stimulated in the period 1994-1998 only through generic instruments. Since then five new biotech specific instruments for research and six for commercialisation have been introduced, with GEN-AU (Austrian Genome Research program) as a broad program covering eight policy goals in total (but excluding the encouragement of business investment in R&D). The profile of the UK was already rather complete in 1994-1998, as almost all policy goals were covered by generic and biotech specific instruments, except for policy goal 4 (human resources) which in the period 2002-2005 was covered by newly created national and regional biotech specific instruments. However, policy goal 8 (ELSA) in 2002-2005 is still covered only by biotech specific and not by generic instruments. The Netherlands has changed its policy since 1994-1998 by introducing new biotechnology specific instruments (including the National Genomics Program and BioPartner) that - apart from stimulating basic and applied research and technology transfer - also support collaboration between disciplines, firm creation, and ELSA activities. In Germany the new biotechnology framework program replaced the 'Biotechnologie 2000' program that ran in the period 1994-1998. Additionally, another 15 new regional biotech specific programs were introduced during the period 2002-2005. All in all, the German policy profile was rather complete in 2002-2005 as it also covered the policy goal to stimulate the availability of human resources (by the National Genome Research Network and the new Framework program 'Biotechnologie') and generic programmes were created that covered policy goals 4 (human resources) and 6 (adoption of technology by industry). In Norway new biotech specific instruments now also cover policy goals to promote interdisciplinary research and the availability of human resources: the 'Molecular medicines and gene technology program' and the 'Etikk, samfunn og bioteknologi' (ELSA) program. The France policy profile still had gaps in 2002-2005. Although new biotech instruments were created to stimulate firm creation (together with generic programs), ELSA activities were not covered by policy-directed instruments. ELSA is performed by one of INRA's research institutes, but in BioPolis this is considered as a non-policy-directed instrument. New biotechnology specific instruments were also created in Italy and Spain. In Italy the policies in place in 2002-2005 show a more thorough coverage of policy goals than in 1994-1998. This has been achieved by regional policies which, through measures like science parks, aim to provide support at various stages of biotechnology development. In Spain new biotech specific instruments have been introduced in the period 2002-2005 that target the promotion of knowledge flow, the availability of human resources and the stimulation of biotechnology adoption by industry. These instruments, launched with the new Foundation Genome España, did not exist in the period 1994-1998. In the other two countries of Cluster 3 new generic programs were in-

troduced only to cover new policy goals: interdisciplinary research (Greece), availability of human resources (Portugal) and to stimulate the adoption of technology by industry (both).

### ***New research priorities***

The Inventory report (Enzing et al. 1999: Vol.1, p.30) summarised future trends in biotech funding; little change was expected in Finland, Portugal, Switzerland, Sweden and the UK. A few countries planned to focus funds on specific areas, with Finland earmarking enzyme technology, France identifying the bio-medical and bio-informatics fields and Iceland selecting bio-medical research on genetics. The other countries clearly did not anticipate the revolution that would be created when the sequencing of the human genome was completed in April 2003. The UK and France had both already established competences in genomic activities through their contributions to the Human Genome Project and, in 1999, France created the National Genopole Network to strengthen French genomic research. In addition, Sweden funded basic research into genomics through its Network Programme as early as 1998. These countries were European pioneers in an area now the focus of many biotech specific initiatives. However, the response by individual countries tends to vary by Cluster.

Countries in Cluster 1 include genomics as part of a wider biotech specific project. For instance, Finland's Biological Functions - Life 2000 Programme includes a section on functional genomics. In Denmark, two biotech specific initiatives focus on applying genomics to areas of national significance: plant breeding and food. Norway funds groups of researchers from industry, public research institutes and universities to carry out research on technological platforms in several areas such as Structural Biology, Proteomics, Microbial Technology, Animal Transgenics and Molecular Imaging, with the aim of enhancing national research in functional genomics. There are no policy-directed programmes in genomics in Switzerland, but a Functional Genomics Research Center has been set up jointly by an Institute of Technology and a university.

With the exception of Ireland, where genomic research is funded by non-policy directed funds or by generic instruments, all the countries in Clusters 2 have significant biotech specific initiatives in genomics. For instance the UK has three programmes: one to help industry to take up the opportunities provided by genomics, a second to study the socio-economic impacts of genomics and the third, with a budget of approximately 77M EUR per annum in the years 2004-05 and 2005-06, supports research on proteomics, including areas such as protein folding and predictive modelling and protein function. The Netherland Genomics Initiative was established in 2002 as a temporary task force. It is within the funding agency, the Netherlands Organisation for Scientific Research, but has relative autonomy. It is dedicated to strengthening genomics-based research and business in the Netherlands. In Austria, one of the few biotech specific programmes focuses on genomics. France has created eight genopoles, each consisting of a regional network of laboratories from different organisations. Each genopole is specialized in at least one of the following areas: Transcriptomics, Structural Genomics, Functional Genomics, Proteomics and Bioinformatics. With the exception of Spain, the countries in Cluster 3 do not have any biotech specific programmes. However, as well as providing funding for a biotech specific programme, Spain has two instruments for research in genomics and proteomics.

Many of the countries in Cluster 1 also have biotech specific programmes in Structural Biology (Finland and Switzerland), Norway also has a program in this area. Systems Biology programs were created in Denmark and Finland (Cluster 1) and Germany (Cluster 2). Bionanotechnology is an emerging area that is beginning to be targeted by biotech specific initiatives (Flanders region in Belgium, France, Italy, UK and Iceland).

#### ***More support for start-ups***

The Inventory report also anticipated that several countries would develop a stronger emphasis on commercialisation activities, especially on start-ups in Austria and Belgium. The national reports show that the majority of countries in Cluster 2 have been active in developing biotech specific programmes to support the provision of seed capital to new biotech start-ups (Austria, France, Germany, The Netherlands and Ireland). The Walloon region of Belgium, Finland, Sweden, Switzerland and Iceland used generic instruments to provide seed capital to start-ups. Several countries in Clusters 1 and 2 have no instruments to provide seed funds for start-up firms (Denmark, Norway and the UK). None of the countries in Cluster 3 have these instruments, although Spain is now making loans to venture capital companies to encourage them to invest in new technology based firms.

#### ***Monitor and support public acceptance of biotechnology***

Biotech specific policy instruments that support the monitoring and improvement of the public acceptance of biotechnology already were at place in the period 1994-1998 in five countries (Belgium, Finland, Germany, Norway and the UK). In another four countries biotech specific instruments were created that also covered this policy goal in 2002-2005 (France, Italy, The Netherlands and Switzerland).

### **6.5 Specialisation patterns in biotechnology**

The relative importance of Red biotechnology (dealing with medical and health issues) was already evident in the funding figures of the period 1994-1998. In the period 2002-2005 Red biotechnology was also the most highly funded area of biotech (see Table 6.4). The relative contribution to the budget spent on Red biotechnology decreased from 58.3% in 1994-1998 to 55.8% in 2002-2005. The expenditure on green biotechnology (including plant biotech, animal biotech and cell biotech that mainly covered food biotechnology issues) accounted for 30.9% of the budget for the three areas in the period 1994-1998 but showed a slight decrease to 28.5% in 2002-2005. However, white biotech has gained importance as its relative share has increased from 10.8% in 1994-1998 to 15.8% in 2002-2005.

Table 6.4 Average annual spending on biotech research in red, green and white biotech through policy directed instruments in the periods 1994-1998 and 2002-2005, for EU15+3 (minus Luxembourg)

	<b>Red biotech</b>	<b>Green biotech</b>	<b>White biotech</b>
1994-1998 (M ECU)	351 (58.3%)	186 (30.9%)	65 (10.8%)
2002-2005 (M EUR)	407 (55.8%)	208 (28.5%)	115 (15.8%)

Note: Annual budget for period 1994-1998 are corrected for inflation according to the harmonised index of consumer prices of 1996 (2005=100) (EUROSTAT)

Sources: Enzing et al 1999 (data for 1994-1998), BioPolis Research

The proportion of the total budget accounted for by red, green and white biotech (in terms of expenditure that could be attributed to these areas) was about 84% in both periods. 'Basic Biotech Research' (including research platforms such as genomics, proteomics) is also an important area, receiving more than any subfield of green or white biotech. In 1994-1998 it was responsible for about 12% of the total funds that could be attributed to biotech areas and in 2002-2005 this figure rose to about 15%. The budget for ELSA activities decreased from 4% in 1994-1998 to 1% in 2002-2005.

Unfortunately it is not possible to show the relative distribution of the funds for the red, green and white areas at the level of the individual countries; nor is this possible to show this for other subdivisions of biotech areas (e.g. subdivisions of these three areas, plus basic research and ELSA) as the funding data are not available for the period 1994-1998. The national reports of the Inventory study only provide these data for a small number of countries.

However, on the basis of a comparative analysis of the rough evaluation of the relative significance of the biotech areas that was made for the Inventory<sup>28</sup> (Enzing et al. 1999: Vol. 1, p. 49) and the BioPolis funding data (section 4.5.2) the following observations can be made about a number of biotech application areas:

- Health biotech: this is the number one area for most of the countries, except for Finland, the Netherlands, Norway and Switzerland. In Switzerland, as in 1994-1998, basic biotechnology research remained the most highly funded biotech area. In Greece and Portugal this still was a moderate area in 1994-1998 and became the number one funded area in 2002-2005.
- Basic research in biotech: This was a focus area only in three countries in 1994-1998 (the Netherlands, Sweden and Switzerland). This area rose dramatically in priority in Norway and Portugal: in 1994-1998 it was a neglected area and in 2000-2005 it received the highest share of funds in relative terms. In Austria and Finland it moved from a moderate area to the number one area.

<sup>28</sup> In the Inventory (Enzing et al. 1999) a ranking was made indicating the significance of the different biotech areas in each country. The ranking was made on the basis of a qualitative assessment of funding activities using the following categorisation: focus area (+), moderate area (0) and neglected area (-).

- Plant biotech: this field received increased priority between 1994-1998 and 2002-2005 in Austria, Germany, France and Sweden and decreased priority in Italy, Norway, Spain and Switzerland. The area kept its relative importance in Belgium and Iceland.
- Animal biotech: Denmark in particular has given this area the highest priority; in 1994-1998 it was still neglected, in 2002-2005 it is the second most funded area (after health). Portugal and Switzerland have also given more priority to this application area in the recent period, but its priority decreased in Ireland and Norway.
- Food biotech: Observations on changes in this area have to be taken with caution as we did not have a similar category in the Inventory. We compare Food (2002-2005) with the Cell Factory category as this mostly included food issues. The field has gained importance in Belgium, Germany and Ireland and has maintained its high priority in Denmark and Switzerland.
- Industrial biotech: There are similar circumstances to those in food; in this case the fields have the same name in both periods, but they do not cover for 100% the same technology/applications (see section 2.2). In Germany its priority has increased dramatically. It has kept its high priority in Finland, the Netherlands and Portugal and lost it in Belgium, Norway and Spain.
- Environmental biotech: This field has gained priority, especially in Iceland, but also in Germany and the UK. It lost its relative priority in the Netherlands.

## 6.6 Future dynamics in national biotechnology policy making

Biotechnology is and will stay a priority area in most of the countries in national R&D and innovation policy. This has been mentioned explicitly by Austria, Germany, the Netherlands, Sweden and the UK. In Luxembourg a discussion is now in progress on choosing biotechnology as a priority. If biotechnology is chosen, substantial funds are needed to improve social acceptance, facilitate the access of SMEs to venture capital, and to attract new company formation. Most likely the focus will be on health biotechnology, especially on immune therapies, diagnostics and vaccine development. In Portugal, the need to prioritize biotechnology fields and improve technology and knowledge transfer has been expressed.

In a number of countries new policy strategies are also under development, and they will also have an impact on biotechnology:

- Belgium: a new horizontal innovation policy will be developed (Flanders), development of Competitiveness Poles (Wallonia) and clustering in three main domains, including biotechnology (Brussels)
- Germany: Policies and future investments (15 000M EUR until 2009 in R&D) of the Federal Ministry of Education and Research will focus on four key fields for action in biotechnology: to promote the knowledge base for product and process innovation in biotechnology, especially in genome research, systems biology and molecular medicine; to exploit the potential of industrial and nanobiotechnology; to promote the valorisation of scientific results and to promote dialogue between industry and society.
- Greece: A new general research strategy will be developed in 2007, also for biotechnology.

- Ireland: A New Strategy on Science, Technology and Innovation for 2007-2013 is in preparation; it will support the continuation of efforts to create a knowledge economy.
- Italy: Biotechnology forms part of the vision for the future development of Italian R&D, but not with a much focused prioritization.
- The Netherlands: The Action Plan Life Sciences of the Ministry of Economic Affairs addresses the importance of entrepreneurship in life sciences, deregulation, enforcement of R&D infrastructure, strengthening of international networks, and clear communication by the government.
- Portugal: There is a New Technological Plan, but it is unclear whether new instruments will be developed.
- Switzerland: Thematic priorities will include stem cell research, biosafety and vaccine research, systems biology, antibiotics, bionano and industrial biotechnology
- UK: A set of recommendations by the Bioscience Innovation and Growth Team for the development of biotechnology include the creation of a National Clinical Trials Agency, a stronger bio-processing subsector through networking four bio-processing Centres of Excellence, and the creation of a Bioscience Leadership Council. For Scotland, a new strategy is under development to achieve critical mass in the life sciences sector by 2020 through focus on human resources, strengthening public and private funding, focus on areas of competitive promise and promoting collaboration between public and private sectors.

In nine countries new biotech research programmes are announced for the next period:

- Belgium: Applied Biomedical Research program (Flanders).
- Germany: BioIndustrie 2021 (Biotechnology in industrial processes) and Nanobio-technology, both introduced in 2006.
- Iceland: Postgenomics Biomedicine Nanoscience and Nanotechnology (3M EUR).
- Italy: Possible incorporation of a selection priority for biotechnology projects in two response mode grant programs.
- The Netherlands: new research programs (total 430M EUR) that also include biotech research: Green Generics Top Institute, two potato genomics projects, additional funds for Top Institute Food Science, Top Institute Pharma, Ecology Regarding Gene Modified Organisms project, Centre for Translational Molecular Medicine, National Biobanks Infrastructure, Knowledge Chain Infectious Diseases Animals and Biomedical Materials. Additional budget for Netherlands Genomics Initiative for second period of five years is under consideration (300M EUR).
- Norway: three new biotech specific programs and five generic programs with a priority for biotechnology were started in 2006.
- Sweden: A new research policy Bill, Research for a Better Life, identifies medical and technological research as priority fields (43.5M EUR in 2005-2008). Establishment of new centres of excellence (32.6M EUR).
- Switzerland: New program on Risks and Benefits of Releasing GMOs (7.75M EUR), new laboratory for special pathogens in the context of research on protection from nuclear, biological and chemical threats and risks (18M EUR) and plans for a new program on new immunisation strategies,

- UK: Within the Technology Program 'Succeeding Through Innovation' DTI has allocated 15.4M EUR for the area of 'Regenerative Medicine Technologies'.

Also five countries announced specific increased efforts to improve the conditions for biotech companies:

- Austria: As announced in RFT's 2005 Strategy paper, increased efforts will be taken to enhance human resources, improve the regulatory framework conditions and to provide better support for start-ups and newly established business.
- Belgium: tax breaks for R&D performing young, innovative SMEs (Federal), improvement of technology transfer (Flanders), (financial) support for start-ups, including spin-offs (Brussels), competitiveness and competence poles, including one in life sciences (Wallonia, Flanders).
- France: implementation of the competitiveness cluster policy (11 of the 67 clusters are related to biotechnology).
- Germany: extension of BioChance Plus after 2007 and of start-up initiatives High-tech Grunderfonds and Go-Bio to promote valorisation and review the Gene Act (in 2006).
- Greece: in general it is expected that high technologies and cooperation with the private sector will remain important for Greece.

No future policy developments were reported for Denmark, Finland and Spain.

## 6.7 Conclusions

Changes to policy-making systems since the period 1994-98 show a growing understanding by governments of the systemic nature of the innovation process. Thus there have been increased efforts to improve policy coordination throughout government, and to foster networks between the knowledge base and firms as well as between firms. The rise in regional government participation in biotechnology policy-making was a major trend in the period 2002-2005. Only a few new research organisations have been set up in the recent period, but there is a growing trend to establish centres of research, some of them virtual centres, that integrate research groups and facilities on one or more university campuses.

Overall, compared to the 1994-1998 period, the funding profiles of the EU15+3 (minus Luxembourg) showed that the average annual funds spent on biotechnology in the 2002-2005 period had almost doubled, with Spain and Italy showing a very large increase. Nevertheless, for the whole group of 17 countries the relative contribution of funding through non-policy directed, biotech specific and generic instruments stayed more or less the same. Considering each of the countries separately, there have been considerable changes to some, from relatively more biotech specific funding to relatively more generic funding, or the reverse. However, there is no consistent pattern of changes in funding profiles within each of the three clusters.

The policy goals' and instruments' profiles also showed considerable change. New generic and biotech specific instruments have been created since 1994-1998. In the period 2002-2005, at least 194 instruments supported biotech R&D, of which 78 were biotech specific; 201 instruments supported

commercialisation, of which 71 were biotech specific. Policy goals that were not covered by instruments in 1994-1998 - most of them dealing with commercialisation - are now addressed by biotech specific and generic instruments. New biotechnology instruments were introduced to cover these new goals, especially in Cluster 2 countries; however, instruments to cover new goals were less frequent in Cluster 1 (only in Switzerland) and Cluster 3 (only Spain and Italy). In many countries genomics and also structural biology and systems biology became a topic addressed in many biotech specific programmes that were created since 1994-1998. Several countries have put stronger emphasis on commercialisation activities, especially on start-ups as many new biotech specific programmes were introduced to support the provision of seed capital to new biotech start-ups.

The relative importance of biotech R&D funding in total government R&D funding has increased in most of the countries, except for Sweden in Cluster 1 and Belgium, Norway and the UK in Cluster 2. It was most interesting to find that Austria and Ireland, which have both improved their overall performance in biotechnology considerably since 1999/2000, had given a much higher priority to funding of biotechnology than in the earlier period. Their previous low performance may have been a reason for policymakers to invest in biotechnology R&D. Austria, which in the period 1994-1998 used only non-policy directed funding measures to support biotechnology, has subsequently created new biotechnology specific and generic instruments covering both science and commercialisation and invested heavily in biotechnology R&D. This may have contributed to the higher performance figure in both science and commercialisations in 2003/04. Ireland has raised its R&D investments considerably since 1994-1998 and also created generic instruments to support interdisciplinary research in biotech and instruments to support firm creation. These new instruments may have contributed to higher recent performance, mainly in science.

The overall specialisation pattern of the EU17 showed some remarkable but still small changes. The relative contributions of Red and Green biotech both decreased in the period 1994-1998 and 2002-2005 with 2.5%: Red biotech to 55.8% and Green biotech to 28.5%. The budget savings were redirected to industrial biotechnology, with the contribution rising from about 11% to 16%. This overall pattern is somewhat scattered when considering individual countries although all had and have Red biotech as their primary field. Some specialisation can be observed where individual countries have become (or stayed) more specialised in plant biotech (Austria, Belgium, France, Germany, Iceland, Sweden), animal biotech (Denmark, Portugal, Switzerland), food biotech (Denmark, Belgium, Germany, the Netherlands), industrial biotech (Germany, Finland, Netherlands, Portugal) and environmental biotech (Germany, Iceland, UK).

In the coming years, biotechnology will stay a priority area in national R&D and innovation policy for most countries. In several countries, governments are developing new policy strategies, which will also have an impact on biotechnology. In some of these new policy strategies, clear and specific goals and actions will be initiated to support biotechnology development. In other strategies it is clear that biotechnology will be supported, but there are no specific actions yet set. In several countries, the governments aim to strengthen the support for collaboration between research and industry as well as for exploitation and commercialisation of biotechnology. In nine countries, governments will develop

and implement new biotechnology research programmes. In most cases, these new biotechnology research programmes are designed to support specific biotechnology research areas. In five countries governments announced new initiatives to improve the conditions for biotechnology companies. These initiatives include improving the regulatory framework, better non-financial support to new firms, raising competitiveness clusters, as well as improved financial support to small firms.



## 7. Policy effectiveness

### 7.1 Introduction

In this Chapter we will explore the effectiveness of various policies to promote biotechnology. It draws together the results of the analysis of national biotechnology policy-making systems (chapter 3), the exploration of policy-directed stimulation of biotechnology in Europe (Chapter 4), the dynamics of biotechnology policy-making (chapter 6) and the performance analysis of the national biotechnology innovation systems (chapter 5). For reasons discussed already in chapter 5 (data availability, historical and institutional conditions for developing biotechnology) this analysis concentrates on EU15+3. All questions related to NMS and AC are discussed in chapter 8.

Our approach is based on the analysis of the current performance of national biotechnology innovation systems, which allows the identification of groups of countries with similar performance (chapter 5). We try to identify past policy activities in these groups of countries that might help to explain current differences in country performance. We are aware of the fact that there is an inherent problem in such an approach because policy activity is just one of several factors that determines the performance of national innovation systems. Other factors that might hinder or support the achievement of policy goals include national economic conditions, institutional, cultural and legal configurations. However, comparing past policy activity with present performance allows the drawing of conclusions about the extent to which certain policy goals have been achieved (even if they have been driven by other factors as well as by policy activity) and thus on the effectiveness of policy approaches.

A second problem relates to the fact that there is a time lag between the date at which the policy is introduced and its results (Reiss et al. 2003). This has been taken into consideration by looking mainly at past policies implemented in the mid 1990s and at the end of the 1990s and current performance of the national biotechnology innovation systems. Based on previous analyses (Reiss et al. 2003, Reiss et al. 2005), we estimate that this time lag is between three and six years depending on the type of policy activity. In the case of general policy configurations which are discussed in section 7.2 we would argue that these are rather inert systems which do not change that rapidly. Accordingly, the exact length of the lag period is not that crucial for such comparisons. For reasons of data availability we compared policy configurations in place around the year 2000 with current performance. Specific policies, for example aimed at supporting the knowledge base for biotechnology, are more flexible than general policy configurations. Accordingly we would expect that such policies would change more easily. Therefore, the precise definition of the length of the lag period for the specific policies discussed in section 7.3 is more important. We therefore compare specific policies in place in the period 1994/1995 with current performance as analysed for the period 2000 to 2004.

## **7.2 Effectiveness and the configuration specific of the national biotechnology innovation system**

In the framework of the national Innovation system in section 7.2.1 we first explore the importance of the macro-level R&D features for interpreting the differences in national performance in biotechnology. Accordingly, in section 7.2.2 specific aspects of the national policy-making process in biotechnology that have a more structural character - such as the different actors involved and their interactions in the decision-making process, the coordination between policy actors at the various levels and the use of policy impact assessments - are evaluated against national performance in biotechnology. Finally, in section 7.2.3 policy profiles, including the sets of specific and generic policy instruments, are assessed against the country's performance in biotechnology and conclusions are drawn on biotechnology policy effectiveness.

### **7.2.1 Macro-level R&D features of the national innovation system and performance**

There are a number of general economic features that constitute the general framework within which each country defines its more specific R&D and innovation policies. These relate to specific choices made within the national systems that deal with the use of R&D and innovation to stimulate economic growth and improve its competitive position in a global economy in order to create favourable socio-economic conditions for its population. These choices, the shape of the national economy and the structure of the industrial sector together shape the conditions for the successful development and implementation of biotechnology in a national system.

The performance of a country in terms of the macro-level indicators for R&D can differ considerably; they also reflect the economic status of the national system. Table 7.1 shows the performance of the 18 countries under review for three macro-level indicators for R&D:

1. Gross Expenditures on Research and Development (GERD) as a percentage of Gross Domestic Product (GDP) is an indicator for R&D intensity of the country's innovation system. It includes investments in research and development of public and private actors.
2. The proportion between public and private expenditures on R&D as percentages of GDP indicates the sources of investments in R&D and the share of investments in R&D of private firms and governments.
3. The third indicator is a proxy for the R&D intensity of the national workforce. It includes the number of researchers as a share of the total number of employees.

Table 7.1 Macro-level indicators for R&amp;D for EU15+3, in 2001

Performance cluster	Country	GERD/GDP	Ratio of business to government R&D expenditures as % of GDP	Number of researchers as share of total number of employees
	Iceland	3.08	1.4	NA
Cluster 1	Switzerland	2.57*	3.0*	5.6 <sup>OO</sup>
	Denmark	2.39	1.9	7.0
	Sweden	4.29	3.4	10.6
	Finland	3.38	2.8	15.8
Cluster 2	Austria	2.03	0.9	4.7***
	United Kingdom	1.87	1.5	5.5***
	Belgium	2.11	2.9**	7.8
	Netherlands	1.88	1.4*	5.5
	Ireland	1.11	2.9*	5.1
	Germany	2.46	2.1	6.7
	Norway	1.60	1.3	8.7
	France	2.20	1.4*	7.2
Cluster 3	Italy	1.11	0.8 <sup>O</sup>	2.8
	Spain	0.32	1.2	4.7
	Greece	0.65	0.5**	3.7
	Luxembourg	1.71 *	NA	NA
	Portugal	0.85	0.5	3.5

NA: no data available

\*: data for 2000; \*\*: data for 1999, \*\*\*: data for 1998; <sup>O</sup> data for 1997; <sup>OO</sup>: data for 1996

Source: OECD S&T Statistics

The table allows a number of conclusions on the relationship between general R&D conditions and performance in biotechnology in a national innovation system:

- The performance levels in biotechnology (in 2004) show high similarities with the R&D conditions measured by the three macro-level R&D indicators (in 2001). General R&D conditions related to the level of national R&D investments, the knowledge intensity of the labour force and to the level of R&D activities of national industry seem to correlate positively with biotechnology performance in the knowledge base and in commercialisation.
- Countries of small economic size and a high R&D intensity are also big players in the field of biotechnology. The countries in cluster 1 have very high R&D intensity (performing close to or above the Lisbon level of 3%), have a very knowledge intensive labour force (Switzerland is the weakest) and companies are the most important R&D actors in their national innovation system (except for Denmark). The biotechnology actors in public research organisations and in industry all seem to profit from these conditions. It can be argued that because of their relatively small size and budgets, and because coordination between actors is easier, they have been able to develop and implement a strategy in which choices have been made and absorptive capacities have been built on a limited set of focussed fields. This might have created

the positive conditions which have led to these countries achieving the best performance in biotechnology.

- Large countries with high R&D intensity in Cluster 2 are Germany and France. Although these countries, and also the United Kingdom might benefit from - in absolute terms - large R&D investments, large internal markets with large leading firms and high numbers of dynamic start-ups in biotechnology, this does not seem to affect their performance in biotechnology as they all belong to cluster 2. There are also differences among them as in France and the UK the contribution of private sector investment is much smaller than in Germany, and the workforce in the UK is less knowledge intensive than in Germany and France.
- Smaller countries in Cluster 2 have higher (Austria, Belgium) and lower (Norway) R&D intensity. In relative terms both Belgium and Ireland have a private sector that is very active in R&D, whilst in Austria this sector is very inactive in R&D. Norway is like other Nordic countries in having a very R&D intensive workforce.

The countries in Cluster 3 have low R&D intensity and a private sector that is not very active in R&D. It might be concluded that these countries have not prioritised R&D and innovation as key mechanisms for economic growth. They can not profit from long-term investment in R&D and higher education or from a private sector that acts as a driving force in innovation processes.

### **7.2.2 Process of policy design and priority setting in biotechnology and performance**

Three aspects of policy processes at the macro level are considered in the analysis in this section: an impact assessment of policies, policy coordination and policy decision-making.

In order to improve and upgrade national policy processes, national policy-makers can collect and evaluate data on the use and effectiveness of their policies and policy instruments, and thereby draw lessons. Impact assessment studies can be made which provide insight in the goals, design, budgets and conditions of policies and policy instruments, the stakeholders involved, and the results and their impacts. This allows them to discuss best practice and what they can learn in order to improve policies and instruments. The second column of Table 7.2 shows that – according to national policy-makers - specific mechanisms have only been implemented in eight countries to assess the impact of policy measures related to biotechnology: the three large West-European countries, Finland, Ireland, Italy, the Netherlands and Sweden (Reiss et al. 2005).

Slightly more emphasis is given to policy coordination. Coordination can take place at several levels. The highest level of co-ordination is where an institution, such as a council, cabinet or a ministry, has responsibility for setting policy priorities across the whole national innovation system. These priorities can serve as policy advice for the government (the institution would be an advisory body) or as binding decisions (the institution would be a policy-making body). Co-ordination among independent ministries, which occurs through an inter-ministerial institution where representatives from different ministries are involved, refers to a medium level of coordination. The institution can have advisory or policy-making functions. A lower level is where a board (or similar committee) is responsible for operational

coordination guaranteeing program coherence among ministries, funding agencies, councils and/or academies. The third column in Table 7.2 shows that nine countries (again based on assessment of national policy-makers) have indicated that they have implemented formal mechanisms to coordinate policy instruments promoting biotechnology: Austria, Belgium, Denmark, Finland, France, Ireland, Italy, Spain and the UK (Reiss et al. 2005).

A classification of the policy decision-making process can be made on the basis of a combination of two related indicators: the number of different actors involved in the process and the intensity of the interactions between these actors. Accordingly, a country with weak interactions is fragmented: actors define strategies with a high degree of independence. The reverse situation is a country where interactions amongst actors are strong and concentrated. The criterion of a multiplicity of policy actors (government bodies, charities, foundations and industry) defining their own strategies takes into account the importance of the policy-making population as well as the relative influence of each of these actors in a country. Accordingly, a differentiation can be made between pluralistic countries (a large number of different actors) and monolithic ones (a low number of different actors). 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, but interaction between them is high have a rather concentrated decision-making process with *ex ante* coordination. The decision-making process is convergent. While the former system encourages diversity, the latter is more targeted.

Table 7.2 Determinants of the biotechnology policy-making process in EU15+3, in the period 2001-2004

Performance cluster	Country*	Impact assessment (2004)	Policy coordination (2004)	Decision-making process (2001)
Cluster 1	Denmark		✓	Convergent (P/C)
	Sweden	✓		Divergent (P/F)
	Finland	✓	✓	Convergent (M/C)
Cluster 2	Austria		✓	Divergent (M/F)
	UK	✓	✓	Convergent (P/C)
	Belgium		✓	Divergent (P/F)
	Netherlands	✓		Convergent (P/C)
	Ireland	✓	✓	Convergent (M/C)
	Germany	✓		Divergent (P/F)
Cluster 3	France	✓	✓	Divergent (P/F)
	Italy	✓	✓	Divergent (M/F)

	Spain		✓	Divergent (M/F)
	Greece	NA	NA	Divergent (M/F)
	Luxembourg			NA
	Portugal			Divergent (P/F)

\*: Iceland, Norway and Switzerland were not covered in both Epohite and Polybenchmark studies. Luxembourg was only covered in the Polybenchmark study.

✓: policy measure is available; blank: policy process is not available; NA: no data available

P: Pluralistic; M: Monolithic; F: Fragmented; C: Concentrated

Sources: Polybenchmark, p. 19; Epohite, p.36

Table 7.2 (third column) shows the characteristics of the decision-making process of the old Member States in terms of Divergence and Convergence with information about the intensity of the interaction between brackets - Fragmented (F) or Concentrated (C) - and about the number of different actors in the process - Monolithic (M) or Pluralistic (P) (Reiss et al. 2003).

In general the table reveals that:

- Countries with convergent innovation systems (*ex ante* coordination of strategic decision-making processes) appear to perform better than divergent ones. For all countries, also the smaller ones, fragmentation of actors seems to be a weakness. Increasing coordination between different policies and between the responsible actors seems to contribute to increasing policy effectiveness. It can be argued that concentration of the strategic decision process for biotechnology by a few actors allows for a visible, stable and coherent policy-making process, leading to higher performance in biotechnology. Here, smaller countries might be structurally in a better position, as they have relatively few actors who know each other well.
- In the countries of Clusters 1 and 2 there is also a higher occurrence of processes of impact assessment and policy coordination. One could expect that countries with convergent decision-making processes also show more policy coordination. However, this is not the case and might be explained by the different levels of the coordination process; with convergent systems using higher levels of coordination and divergent systems lower levels.
- Almost all countries in Cluster 3 are monolithic and they do not coordinate their research and innovation strategies *ex ante*, which leads to a fragmented system. Portugal is an exception in this cluster, as the policy process shows rather weak interactions in the decision-making process in which a large number of actors are involved.

### 7.2.3 Effectiveness of biotech policies

BioPolis shows that a broad set of biotech specific and generic policy instruments have been created in order to promote high quality research and stimulate valorisation and innovation in biotechnology in Europe. In order to draw conclusions about the policy effectiveness of specific policy profiles over others, and to take into account the time lag between implementation and the results of policies, the data on the policy profiles of the Old Member States in the period 1998-2001 gathered in Epohite (Reiss et al. 2003) will be used together with the performance data for 2004, collected in BioPolis.

Epohite considered a broad policy profile, which – apart from the biotech specific and generic policy instruments of BioPolis - also included three generic instruments that promote the non-technical conditions for innovation:

- regulation concerning stock markets or product quality and labelling;
- measures to regulate intellectual property rights (IPR);
- measures to assure the availability of financial capital in high-growth sectors to stimulate S&T.

Table 7.3 presents the profile of each of the countries in the three clusters based on this broad set of policies; ranging from high importance (15) to not important (0)<sup>29</sup>.

Table 7.3 Biotechnology policy profiles of EU15 (minus Luxembourg), 1998-2001

	Biotech specific policies			Generic policies				Total (sum)
	Know- ledge base	Commer- cialisa- tion	ELSA	S&T poli- cies	Regu- lation	IPR legis- lation	Capital availabil- ity	
<i>Cluster 1:</i>								
Denmark	10	9	9	12	3	9	15	67
Sweden	10	9	15	9	na	3	9	55+
Finland	8	10	9	14	9	12	12	74
<i>Cluster 2:</i>								
Austria	6	11	9	11	6	9	6	58
UK	13	12	9	11	6	9	3	63
Belgium	9	9	9	12	6	8	13	66
Netherlands	15	13	9	13	12	9	9	80
Ireland	8	12	3	13	9	9	9	63
Germany	11	9	12	14	9	9	15	79
France	8	9	3	9	6	6	6	47
<i>Cluster 3:</i>								
Italy	5	6	3	5	3	3	6	31
Spain	7	6	3	5	3	3	6	33
Greece	3	3	3	13	3	3	12	40
Portugal	9	6	0	3	0	6	0	24

Source: Epohite country reports

The message from the table is rather clear: public policies matter. The general conclusion that can be drawn is that countries that have policy profiles that give high importance to a broad set of policies are more successful than countries where the policy profile reflects only low importance for policies. .

More specific conclusions on the effectiveness of biotechnology policy profiles are:

29 The assessment of importance has been made for each country on a comparable way and according to their relevance and the emphasis to the specific instruments in the national policy system.

- All countries of Cluster 1 (Sweden has no score for regulation) and of Cluster 2 (except for France, which scores relatively low), have policy profiles with high total importance scores. Their profiles include both generic and biotech-specific public policies with high importance levels, which also cover policies both to support the knowledge base and commercialisation. The Netherlands and Germany are exceptions, as generic S&T policies have relatively more importance than biotech specific policies. Countries that give less importance to creating biotech-specific and generic instruments for the stimulation of biotechnology also perform more weakly.
- Generic S&T policies are of higher importance in the policy profile than biotech specific S&T policies in all countries except for Sweden, UK, the Netherlands, Spain and Portugal. In the period 1998-2001 biotech specific commercialisation policies were of higher importance than biotech specific S&T policies in only Finland, Austria, France and Ireland.
- In better performing countries, policies addressing the ethical legal and social aspects (ELSA) of biotechnology are as important as biotech S&T and commercialisation policies (especially in Sweden and Germany).
- A similar conclusion can be drawn about the importance of policies that address the conditions for industry (regulation, capital): better performing countries have profiles in which these policies are of higher importance than in lower performing countries.

## 7.3 Effectiveness of specific policies for biotechnology

### 7.3.1 Policies to support the knowledge base for biotechnology

To explore the effectiveness of specific policies that aimed to support the knowledge base for biotechnology, the following types of policies and parameters were examined: policies supporting basic research, policies supporting industry-oriented and applied research, policies fostering the international mobility of researchers, policies supporting higher education in biotechnology and regulations made in order to foster innovation and create attractive framework conditions for biotechnology research. With respect to these policy types the intensity of policy activity for each type and the relationship between different types on the one hand and between generic and specific approaches on the other hand were considered. Information on the various policies in place in the relevant countries during the mid 1990s was retrieved from the policy benchmarking project (Reiss et al. 2005). In order to identify any policy effects on performance, countries for which policy information was available were ranked according to their performance in terms of generating and maintaining the biotechnology knowledge base as described in chapter 5. Table 7.4 summarises the available information. Policy intensity is scaled between 0 and 5, where 5 corresponds to the highest intensity as explained in the policy benchmarking project (Reiss et al. 2005), while 0 indicates no policy activity.

As a starting point for the analysis, the share of public funding devoted to biotechnology in total public R&D was taken into consideration (data see chapter 4). This analysis indicates that the share of biotechnology funding, which could be considered an indication of the priority of biotechnology within the national innovation system, does not explain differences in knowledge base performance. We find

countries with low shares of biotechnology funding in the top performing group (e. g. Sweden, Denmark and Finland) as well as in the country group performing below the European median score (e. g. France and Germany). The same holds true for high shares of biotechnology funding. Ireland and Austria are examples of countries performing well with high shares of biotechnology funding, while Spain is an example of the opposite type: a high share of funding and below average performance.

Table 7.4 Policy activities in place in 1994/95 in EU15 (minus Greece) to support the biotechnology knowledge base

	Basic research		Industry-oriented research		International mobility		Human resources	Regulation	Performance
	BS	G	BS	G	BS	G	BS	G	score
<i>Cluster 1</i>									
Sweden	4	5	3	2	0	5	5	3	8.05
Denmark	5	na	4	na	3	1	na	0	7.62
Finland	2	4	3	4	2	4	4	na	7.14
<i>Cluster 2</i>									
Austria	0	2	0	5	0	1	0	0	5.66
United Kingdom	5	0	1	0	0	0	4	na	5.55
Belgium	5	3	5	3	0	1	4	na	5.64
Netherlands	2	5	4	5	0	0	4	5	6.31
Ireland	3	2	5	0	0	1	4	na	5.87
Germany	3	5	4	3	1	1	2	2	4.53
France	0	3	0	3	0	2	5	3	4.48
<i>Cluster 3</i>									
Italy	0	3	0	2	0	2	5	3	3.79
Spain	0	2	0	3	0	2	5	2	3.59
Luxembourg	0	3	0	3	0	0	na	na	2.72
Portugal	5	1	3	1	0	3	na	1	3.02
USA	4	4	5	4	na	na	4	na	

BS: biotech specific G: generic

na: not data available

Sources: Reiss et al. 2005; BioPolis Research

Looking at policy activities supporting basic and industry-oriented research (Table 7.4), we observe that most of the highly performing countries are characterised by a balance of specific and generic instruments. Among the countries performing below the average we find either a strong focus on specific measures only - such as in the UK or in Portugal - or mainly generic instruments as is the case for France, Italy or Spain. This observation seems to indicate that having only generic instruments in

place is less effective. Specific instruments seem to be more beneficial. However, the balance between specific and generic instruments is more important. A similar effect can be observed for the balance between the support for basic and applied research. Most highly performing countries gave equal emphasis to both areas or had some stronger focus on supporting basic research.

In order to interpret this pattern of policy effectiveness (balanced policies are most effective), it is worth looking at the status of biotechnology in the mid 1990s when the observed policy configurations were in place (sources: OECD 1996, James 1997). During that period a number of biotechnology-derived drugs had already entered the market. The Human Genome Project had been running since 1989. However, large-scale parallel high-throughput approaches that finally led to success for this project had not yet been developed. In the agro-food area, the first transgenic crops with herbicide tolerance or pest resistance had become available and in 1994 the first product - the Flavr Savr® tomato - was approved. In the case of environmental applications, the focus was on waste treatment and bioremediation. Process-integrated biotechnologies, which are known today as white biotechnology, were not yet well developed.

This short review shows that some avenues for future development and application of biotechnology were already visible. However, at that time scientific and technological approaches which are widespread today, such as all the "-omics" sciences and later on systems biology approaches trying to integrate and understand the wealth of information created from "-omics", were far away. Accordingly, countries that supported both the advance of knowledge in specific fields of biotechnology and also took care to maintain the broad knowledge base were ready to participate in new and unexpected developments. They had advantages over countries that focused too closely on one or the other area of biotechnology, or countries that had only generic approaches in place, and neglected the creation of a specific knowledge base.

Support for the international mobility of researchers in general did not gain high attention among the countries considered. However, where it has been implemented (e. g. in Sweden or Finland) it seems to be beneficial to the output. This observation is in particular relevant for smaller countries which depend to a greater extent on an international workforce due to the (natural) limitations in the diversity of their domestic knowledge base.

Support for the development of human resources in biotechnology does not seem to make a difference in terms of performance. In the mid 1990s, every country had the means in place to support higher education in biotechnology. Obviously, having qualified staff for biotechnology is a necessary but not a sufficient condition for creating high output in terms of knowledge base performance. Other factors also seem to be important, such as the availability of research facilities, funding, infrastructure and cooperation partners.

Finally, regulations fostering research activities such as protecting the intellectual property produced by public research organisations or providing suitable regulatory frameworks for carrying out funda-

mental research seem to make no difference in terms of performance. Again, these seem to be necessary but not sufficient factors for success.

### 7.3.2 Policies to support knowledge transfer and commercialisation in biotechnology

In analogy to section 7.3.1, this section explores the effectiveness of policies aimed at exploiting and commercialising the results of biotechnology research. Policy instruments in place in the mid 1990s were compared with actual performance in biotechnology as described in section 5. Four types of policy approaches were included in the analysis: Those supporting the exploitation of biotechnology (including e. g. the establishment of technology transfer offices at universities, financial support for scientists willing to patent their research, IPR courses, grants for writing business plans, financial support for spin-off formation, incentives for collaborative research between industry and public sector research organisation); support for firm creation; the specific stimulation of biotechnology research in industry; and creating supportive regulatory framework conditions for commercialisation.

The relevant policy instruments, characterised by their intensity and the performance scores of the countries considered, are summarised in Table 7.5. The analysis of policy approaches aimed at the exploitation of biotechnology indicates that all highly performing countries had generic and biotech specific instruments in place. All those countries performing below the European average also had generic instruments but a number of these countries did not use biotech specific policy instruments, France and Italy are extreme examples with very high generic and zero biotech specific activity. A similar observation was made for policies supporting firm creation. These observations support the notion that generic exploitation approaches are not sufficient by themselves. Rather a well balanced mix of generic and biotech specific measures seems to be superior.

Table 7.5 Policy activities in place in 1994/95 supporting knowledge transfer and commercialisation

	Exploitation		Firm creation		Industrial research	Regulation	Performance
	BS	G	BS	G	BS	G	score
<i>Cluster 1</i>							
Denmark	2	4	3	4	0	0	13.65
Sweden	3	2	0	2	1	1	9.72
Finland	2	4	2	3	4	na	6.47
<i>Cluster 2</i>							
Austria	2	2	1	1	3	0	5.53
United Kingdom	2	1	1	2	0	na	5.32
Belgium	4	4	3	3	0	na	4.76
Germany	3	2	3	3	3	2	4.24
Netherlands	2	3	1	2	1	1	4.04

France	0	5	0	2	0	3	3.46
Ireland	2	2	2	1	1	na	3.34
Luxembourg	0	1	0	0	0	na	1.03
<i>Cluster 3</i>							
Spain	0	2	0	1	0	1	0.99
Italy	0	5	0	2	0	2	0.79
Portugal	0	1	0	2	3	1	0.24
USA	0	3	2	3	4	4	

na: not data available

BS: biotech specific G: generic

Sources: Reiss et al. 2005; BioPolis Research

The USA does not comply with this general observation with respect to exploitation, having in place only generic instruments. This difference between the USA and most European countries that perform well might be related to the advanced stage of development of the sector in the United States, where generic approaches might be more appropriate.

The analysis of support measures for biotechnology research in industry reveals ambiguous results. We observed very low policy activity in highly performing countries as well as in poorly performing countries. Based on these results, no clear conclusions can be drawn on the effectiveness of such policies.

Judging the effect of the regulatory framework is complicated by a lack of data for a number of countries. The available information suggests no clear relationship between regulatory framework and performance. However, looking at the situation in the United States reveals that it gives strong emphasis to creating a supportive regulatory framework for commercialising biotechnology.

## 7.4 Conclusions

The analysis of policy effectiveness shows that policies that include both generic and biotech-specific public policies with high importance levels and which support science base and commercialisation activities are more successful (i.e. show higher performance levels) than countries that give low importance to their policies. Countries that give less importance to creating biotech-specific and generic instruments for the stimulation of biotechnology also perform more weakly. In other words: public policies matter.

The analysis of the effectiveness of specific science base policies seems to indicate that having only generic research stimulating instruments in place is less effective; biotech specific instruments seem to be more beneficial. However, keeping a balance between specific and generic instruments and between support of basic and applied research also seems to be important. Most highly performing countries gave equal emphasis to both basic and applied research or had some stronger focus on

supporting basic research. Where support for international mobility of researchers has been implemented it seems to be beneficial to the output. This is particularly relevant for smaller countries that have limitations in the diversity of their domestic knowledge base. Support of the development of human resources specialised in biotechnology and regulations fostering research activities seem to make no differences in terms of performance.

The analysis of policy approaches aimed at the commercial exploitation of biotechnology indicates that all highly performing countries had in place generic and biotech specific instruments. All those countries performing below the European average also had generic instruments but a number of these countries did not use biotech specific policy instruments. No clear conclusions could be drawn on the effectiveness of policy support measures for biotechnology research in industry or about the effect of the regulatory framework. These observations support the notion that generic exploitation approaches only are not sufficient. Rather a well balanced mix of generic and biotech specific measures seems to be superior.

However, performance levels in biotechnology show high similarities with the R&D conditions measured by the three macro-level R&D indicators. General R&D conditions related to the level of national R&D investments, the knowledge intensity of the labour force and to the level of R&D activities of national industry seem to correlate positively with biotechnology performance in the knowledge base and in commercialisation. When the conditions for R&D attain a high level, a knowledge intensive environment is created in which biotechnology – because of its science driven character - can grow and expand its impact on science, the economy and society.



## **8. Biotechnology policies and performance in New Member States and Accession Countries**

### **8.1 Introduction**

This chapter presents information about biotechnology research and commercialisation in the 10 Member States that joined the European Union in May 2004 (Hungary, Poland, the Czech Republic, the Slovak Republic, Slovenia, Estonia, Latvia, Lithuania, Malta and Cyprus), as well as the two which joined in January 2007 (Bulgaria and Romania) and a further two which are in accession negotiations (Croatia and Turkey). They are a very heterogeneous set of countries, ranging in population from less than 0.5 million (Malta) to 71 million (Turkey). The eleven countries of Central and Eastern Europe (CEE) share the legacy of central planning under the Communist regime and in this they differ from the three Mediterranean countries. However, what all these countries have in common is that they were late to exploit the biotechnology revolution. Some of the New Member States (NMS) and Accession Countries (AC) were unable to provide full information about the policies and related expenditure for promoting biotechnology research; the content of this chapter must therefore be treated with great caution.

Throughout this chapter, we group the countries into three clusters of countries with similar performance in biotechnology, as it forms the basis for distinguishing shared characteristics which may help to explain performance. The next section of this chapter provides the context for policy-making in the 14 countries, in terms of the way in which their policy-making systems are configured. Section 8.3 discusses the instruments used to promote biotechnology and the funds allocated to these measures as well as any planned developments for biotechnology strategy. The fourth section presents the science and technology (S&T) indicators used to identify clusters of countries with similar performance, with a preliminary discussion of the difficulty of using S&T indicators for NMS and AC, especially for CEE countries. It also presents the imperfect S&T indicators that are available for various aspects of these countries' performance in biotechnology research and commercialisation. The chapter concludes by identifying policy characteristics, which appear to either help or hinder biotechnology development.

### **8.2 Configuration of policy-making systems**

This section will present some basic data about the context for policy-making, in terms of some general economic characteristics of the 14 countries, because this sets the strategic framework within which each country can define its R&D and innovation strategy. It will then present the policy-making systems of the three clusters of countries with similar performance in terms of (i) the main policy actors involved, coordination between the policy actors and the agencies involved in distributing research funds; and (ii) the researcher performers.

Before presenting these general characteristics, it is relevant to mention the shared heritage of the science systems of CEE countries that emerged from the regime of central planning during the Com-

unist period. The science system was organised into three separate sectors, each with distinct functions. The National Academies of Science carried out basic research in institutes for the main disciplines and funding was allocated to these institutes, not to individuals or research groups. The heads of these institutes, Academicians, were responsible for making science policy to meet the plans set by their political masters and for coordination. Except for Poland and Hungary, where universities performed a significant amount of research (Radosevic and Auriol 1999), the higher education sector was devoted exclusively to education but, over time, it undertook some research, for instance work on research degrees. However, because the Academies and the universities competed for the same budget, there was unhealthy rivalry between them. The third sector, applied research and development, was carried out in industrial research institutes under specific ministries and was completely separate from the enterprises and there was little in-house industrial R&D (Balázs et al. 1995). The Czech Republic and Slovakia differ from this general pattern and over half of R&D was performed in the business sector (Radosevic and Auriol 1999). The economic crisis of the transition period, after 1989, led to a dramatic decline in resources for the research system (Balázs et al. 1995), and the system began to be restructured. The two main features of the restructuring are increased autonomy for scientists and the beginnings of competitive research funding (Kozlowski et al. 1999). Although the system is still in transition, Radosevic and Auriol (1999) foresee a "new division of labour" for national R&D systems in the long-term, and convergence with the R&D model of market-based economies in which business enterprises will perform R&D, and academic institutes and universities will be involved in basic research.

The two Mediterranean countries also have specific characteristics that need to be taken into account. Until 2005, Malta had no means of supporting R&D, except from meagre resources available from its sole university. GERD as a percentage of Gross Domestic Product (GDP) stood at only 0.26% in 2003. It rose to 0.63% in 2004, with the establishment of a programme to fund research. Cyprus does not have a long history of science and technology research. However, for over 45 years the government has been actively supporting research and implementing measures to control an inherited genetic disorder – thalassemia - that affects over 14% of the population.

### **8.2.1. General characteristics**

The main characteristics of the 14 countries in terms of their population, the intensity of R&D expenditure as shown by gross domestic expenditure on R&D (GERD) as a percentage of gross domestic product (GDP) and the existence of strong industrial sectors with the potential to exploit biotechnology are shown in Table 8.1. None of the countries reach the EU-25 average for GERD as a percentage of GDP, which was 1.86% in 2004; most are significantly below this figure. The industrial sectors relevant to biotechnology in the majority of the countries are traditional areas such as agriculture and the food and drink industry; several countries are involved in pharmaceuticals production.

The experience of the transition period made it difficult for some CEE countries to maintain or develop their biotechnology capabilities related to the pharmaceuticals sector. For instance, prior to the collapse of communism, Bulgaria produced antibiotics and had good research capabilities in fermenta-

tion technology and pharmaceutical biotechnology. As a consequence of the transition period, biotechnology-related capacities, infrastructures and resources deteriorated. Biotechnology products had been designed mainly for domestic use and for export to the Eastern Block countries. There was a collapse in demand from these markets, and Bulgaria was unable to enter new markets in the West because its products did not meet the requirements for handling genetically modified organisms.

Table 8.1 General economic features of NMS and AC

Country (Population)	GERD/GDP 2004*	Sectors relevant to biotech
<i>Cluster 1</i>		
Slovenia (1.99M)	1.45%	Pharmaceuticals
Czech Republic (10.2M)	1.26%	Chemicals, pharmaceuticals
Hungary (10M)	0.88%	Food, pharmaceuticals
Estonia (1.35M)	0.88%	Food & drink, wood processing
<i>Cluster 2</i>		
Slovakia (5.4M)	0.51%	Agriculture, food & drink
Cyprus (0.73M)	0.37%	None
Croatia (4.4M)	1.22%	Pharmaceuticals
Poland (38.2M)	0.56%	Food
<i>Cluster 3</i>		
Malta (0.4M)	0.63%	None
Lithuania (2.5M)	0.76%	Research materials, bio-pharmaceuticals, bioremediation
Latvia (2.3M)	0.42%	Food, wood processing
Bulgaria (7.7M)	0.51%	Brewing, dairy products, antibiotics <sup>a</sup>
Turkey (70M)	0.66% <sup>b</sup>	Agriculture
Romania (21M)	0.39%	Agriculture

<sup>a</sup>: Bulgaria mainly served Eastern bloc countries prior to 1989. Biotechnology capacities degenerated during the transition period because Bulgarian products failed to meet Western European standards. <sup>b</sup>: 2002

Source: Eurostat website

### 8.2.2 Science and technology policy actors

The configuration of the policy-making and research funding systems in many NMS and AC has undergone many changes since the early 1990s, with frequent changes to Ministry responsibilities, the policy-making system, the agencies responsible for funding science, technology and innovation and their methods for funding research. Precise information on some of these issues is not fully available for all countries but rough judgments have been made from the facts that are accessible.

In most countries, responsibility for scientific research policy is vested in the Ministry for Education and Research (or similar) and responsibility for innovation policy in the Ministry of the Economy (or similar). The exceptions are Romania, where the Ministry of Education and Research is in charge of R&D and Innovation policy, and Croatia, where the Minister of Science, Education and Sport has responsibility for science and technology policy.

Every country has an advisory body to support ministries in their policy-making and contribute to coordination of science and innovation policy across government. Strong coordination of policy is supported by representation on advisory bodies by a wide range of actors with interest and knowledge relating to research and/or innovation policy. These actors include research funding agencies, the academic community and industry as well as ministers for agriculture, health or the environment, and national Academies of Science that have responsibility for science in their own institutes. In countries where there are separate advisory panels for science policy and innovation policy, coordination is supported by cross representation on each other's panels.

The academic community usually has some involvement in advising government on science policy. In most countries, this involvement is weak. There is less evidence of industrial involvement in innovation policy. Table 8.2 indicates how far each type of actor is involved in science, technology and innovation (STI) policy together with a judgment about the degree of policy coordination or fragmentation in each country. The judgment recognises that the need for coordination may be more important in large countries than in very small ones. The table is a qualitative assessment, based on the information contained in the national reports.

Table 8.2 Estimated influence of key players involved in policy-making for S&T and Innovation

Slovenia	●●			○	●	●	●●	Policy integration across government and with external actors
Czech Republic		●●	○	○		●	●	Policy integration across government and with academic community. No industry participation
Hungary		●●		○	○	○	●●	Policy integration across government and with external actors
Estonia	●●			○	○	●	●●	Integrated STI policy
<i>Cluster 2</i>								
Slovakia	●●			○	○	○	○	No industry participation. Weak links between S&T and innovation policy
Cyprus		●●	●	n.r.	○	○	●●	Membership of committees/panels ensures coordination
Croatia	●●				○	○	●	STI policy integrated in single Ministry
Poland		●●				○	○	No industry participation
<i>Cluster 3</i>								
Malta	●●		●	n.r.		○	○	Weak links between science and innovation policies

Lithuania	●●				●	○	No industry participation; weak links between Research and Economy Ministries
Latvia	●●				○	○	No industry participation
Bulgaria	●●			○	○	○	Weak links between science and innovation policies
Turkey		●●			●	○	University autonomy in use of research funds; no industry participation
Romania		●●		●	○	○	No industry participation

Strong ●● Moderate ● Weak ○ Not relevant n.r.

Source: BioPolis Research

Another element affecting coordination is the extent to which research funds are allocated by research councils through a competitive, peer-reviewed process or in the form of block grants to Institutes. Previous research suggests that the former system allows *ex ante* coordination, before the implementation of strategic decisions. By contrast, the funding of research through the allocation of block grants gives autonomy to organisations over the research agenda, and coordination can only be carried out *ex post*. Moreover, competitive research funding by research councils is not only flexible, it appears “to be a more effective method to achieve higher scientific performance than direct control of funds by research institutions” (Reiss et al. 2003). Some CEE countries have now adopted or are moving to the former method, but a high proportion of research funding is still allocated as block grants to Institutes and/or universities in many of these countries. However, these funds may be allocated to Institutes dedicated to a specific area of research, e.g. molecular biology. The agencies that fund research are normally separated from those that fund its commercialisation through support to applied research, technology development, industrial research grants, university-industry research collaboration and measures to encourage the creation of small firms. To the extent that information is available, Table 8.3 presents information about the funding agencies that exist in each country and the activities they support.

Table 8.3 Organisations funding research and type of funding

Country	Organisation	Type of funding
<i>Cluster 1</i>		
Slovenia	Slovenian Research Agency Slovenian Science Foundation Ministry of Economy Government sources	Competitive grants for scientific and applied research Grants for young researchers Use of PSR research by industry, research cooperation and promoting foundation of new firms Core funding for public research institutes
Czech Republic	Min. Education Youth & Sports Min. Industry & Trade Grant Agency of the Czech Republic Academy of Sciences Various Ministries	Funds research programs at universities Grants for industrial research projects Competitive grants for public and private sector research Competitive basic research grants for researchers in its institutes (core funds from government) Grants for public and private sector research
Hungary	KPI OTKA Academy of Sciences Bay Zoltan Foundation Various Ministries	Competitive grants for R&D and for innovation projects involving academic-industry collaboration; promoting public-private partnerships; promoting creation of high-tech firms and innovation by SMEs Competitive grants for basic research in public sector Block grants to institutes Applied R&D in own institutes Support research in sectoral institutes

Estonia	Estonian Science Foundation	Competitive grants for basic and applied research by universities and institutes
	Enterprise Estonia	Supports science/industry collaboration and Centres of Excellence in research
<i>Cluster 2</i>		
Slovakia	Academy of Sciences	Block grants to institutes
	Agency for Support of R&D	Competitive research grants (public and private)
	Scientific Grant Agency VEGA	Competitive grants for basic research (public)
	NADSME	Supports innovation by firms in regions
Cyprus	Research Promotion Foundation	Competitive project grants for scientific and technological research by public and private sector research, for collaboration within the public sector and with industry; grants for infrastructure
	Various Ministries	Institutional support for relevant institutes
Croatia	Min. for Science Education & Sport	Grant for fixed operating costs of Institutes Competitive project grants for scientific research and technological development by universities and public research institutes
	Nat. Foundation for Science Higher Education and Technological Development	Support for strategic areas of science: project grants, infrastructure grants, and support for technology transfer and innovation; grants for scientists to relocate in Croatia; funding for new posts for young researchers in the public sector
	BICRO	Support for innovative firms and science-industry cooperation

Poland	Min. of Education & Science	Grants for response mode, commissioned and strategic research; block research funds for universities
	Department of Innovation	Block grants to Academy of Science Institutes
	PAED	Block grants to R&D Institutes
	Foundation FIRE	Funds for SMEs to support innovation
		Support for innovative start-ups
<i>Cluster 3</i>		
Malta	Malta Council for Science and Technology	Project grants for public and private research; grants for research for SMEs or for collaboration with SMEs
	Malta Enterprise	Training and knowledge transfer grants for start-ups
Lithuania	Lithuanian State Science and Studies Foundation	Individual and project grants
	Academy of Science	Block grants to Institutes
Latvia	Latvian Council of Sciences	Competitive project grants for public research organisations
Bulgaria	Nat. Fund for Scientific Research	Has moved to competitive principle for distributing grants; no further information
	National Innovation Fund	Market-oriented applied research projects; promotes links between research institutes, industry and SMEs
	Academy of Science and Centre of Agricultural Science	Block grants to Institutes

Turkey	Min. of Finance	Block research funds for each university
	State Planning Organisation	Research projects and infrastructure for universities
	Tubitak	Research projects in universities, public and private organisations; block grants to its own Institutes
	TTGV	Technological development projects; university-industry collaboration; support to start-ups
	KOSGEB	Stimulate innovativeness of SMEs
	Undersecretariat of Foreign Trade	Project grants for private sector
Romania	Min. Education & Research	No. information on how funds allocated
	Romanian Academy	Block grants to Institutes

Source: BioPolis Research

Table 8.4 shows the institutional actors performing biotechnology research in each country and the number of each type of institution. Some of these institutions concentrate completely on biotechnology; others conduct biotechnology research on specific topics, as part of a broader programme of research. An emerging trend (mainly in cluster 1 countries) is the use of research instruments that encourage networking between researchers in Institutes and universities, and/or with industry e.g. virtual centre of excellence for biotechnology in Slovakia, the Estonian Biocentre, the research centre programme of the Czech Republic, Hungary's innovation cluster programme and a programme of the Research Promotion Foundation in Cyprus.

Table 8.4 Institutional actors performing biotechnology research

Country	Universities	Academy of Science Institutes	Other public research institutes/centres
<i>Cluster 1</i>			
Slovenia	2	-	6
Czech Republic	6	10	2
Hungary	✓ *	2	3
Estonia	3	-	6

<i>Cluster 2</i>			
Slovakia	3	7	-
Cyprus	1	-	3
Croatia	✓ *	-	5
Poland	21	10	-
<i>Cluster 3</i>			
Malta	1	-	-
Lithuania	2	2**	1
Latvia	-	-	6***
Bulgaria	5	6	16
Turkey	11	2****	4
Romania	3	1	6

✓\*no data available; \*\*: 1 located at university; \*\*\*: located at 2 universities; \*\*\*\*Tubitak institutes

Source: BioPolis Research

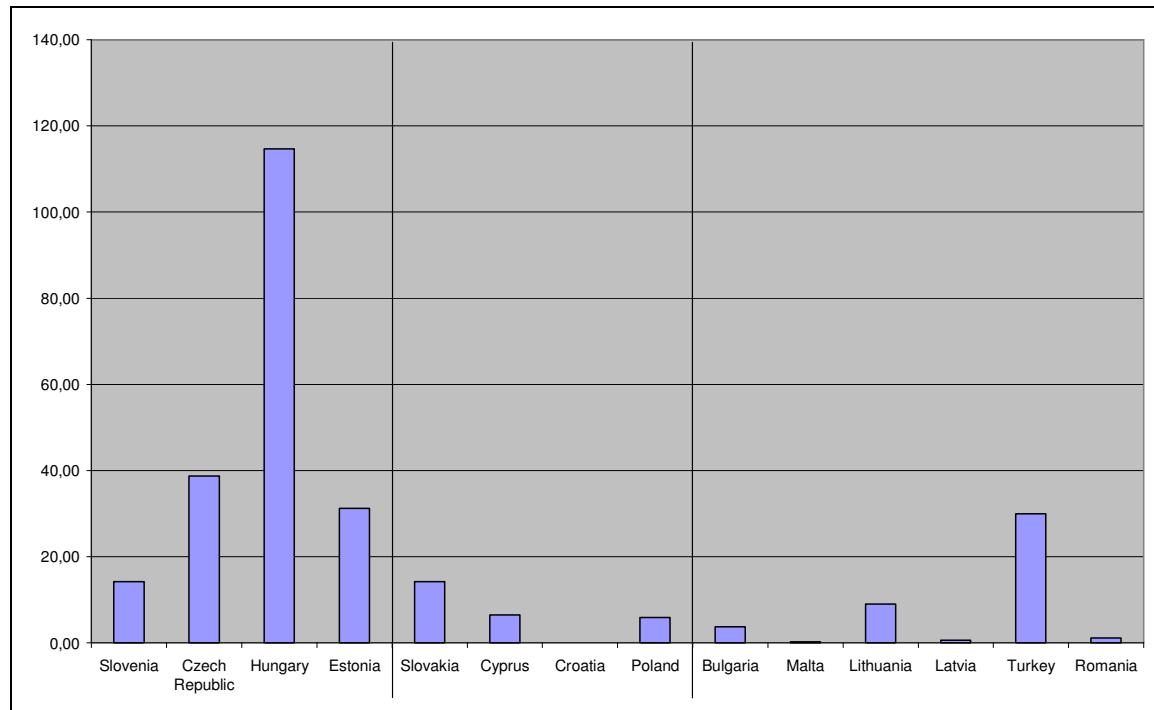
### 8.3 Funding of biotechnology

This section presents data about the funding of biotech research in the NMS and AC. As mentioned in Section 8.1 above, some countries were unable to provide full information about expenditure on biotech research and therefore Figures 8.1 and 8.2 should be treated with caution. No data on funding was available for any Croatian programmes and the amounts for Bulgaria, the Czech Republic, Romania and Turkey are underestimates, as we could not get expenditure information for several national programmes. The data for Turkey, for example, mainly reflects funding by Tubitak, which only provides around 10% of public funding for academic research. In addition, these figures do not reflect much of the research in universities or Academy of Science Institutes that is funded through block grants (see Table 8.3 above). The gaps in the data on funding of biotechnology in NMS/AC mean that the following figures give an indication of **minimum** total expenditure by all 14 countries only. Thus, our calculation of total expenditure on biotech research and commercialisation of 398M EUR must be regarded as a rough estimate. It represents only 2.84% of all expenditure on biotech research in the 32 countries covered by this

Report, but we doubt that the percentage contribution would be much higher even if fuller data on biotech expenditure had been available.

Figure 8.1 shows that, in absolute terms, the countries in Cluster 1 are spending much more on biotech research than the other countries.

Figure 8.1 Total budget for biotechnology (M EUR)

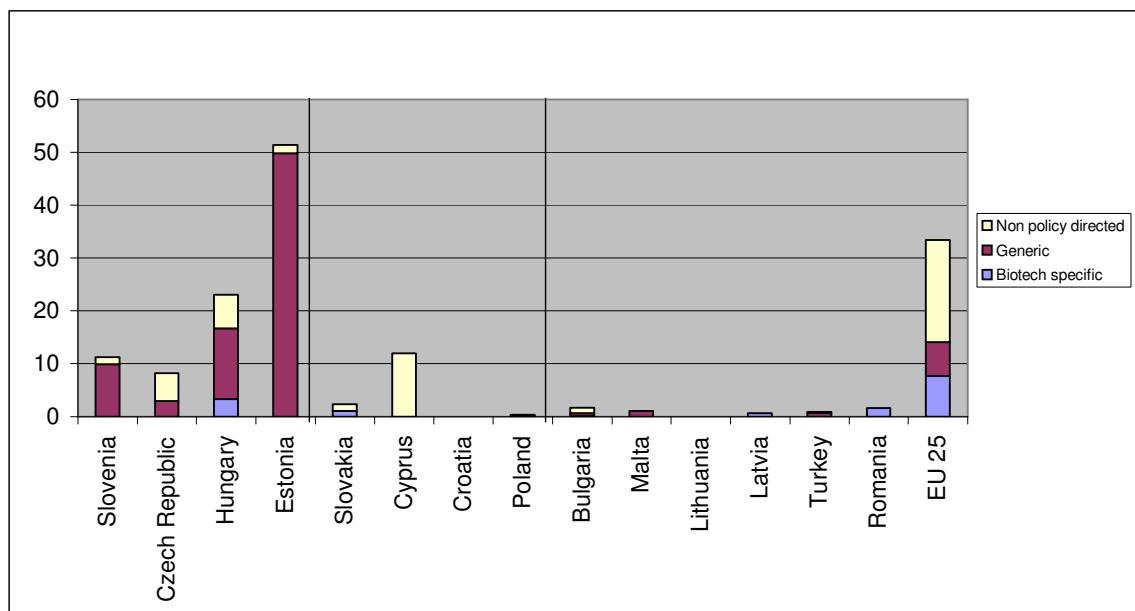


Source: BioPolis Research

To provide a fairer comparison, Figure 8.2 adjusts the data for each country in terms of its population and its purchasing power. It also shows the proportion of each country's budget which is policy directed, covering both generic and biotech-specific policy, as well as the non-policy directed funding.

Figure 8.2 shows that Cluster 1 countries also spend more than countries in other clusters in relative terms and identifies Estonia as the only country among the NMS/AC to spend above the average of the EU-25. Figure 8.2 also shows that NMS and AC countries spend a higher proportion of funds on policy directed funding generic instruments than the average for the EU-25, and very little on biotech-specific instruments. It also suggests that spending on non-policy directed expenditure is below the EU-25 average. We believe that this is a distortion, caused by the inability to collect information on biotechnology expenditure through non-policy directed block research grants for Institutes and universities.

Figure 8.2 Total budget for biotechnology in M \$ PPP per Million Capita



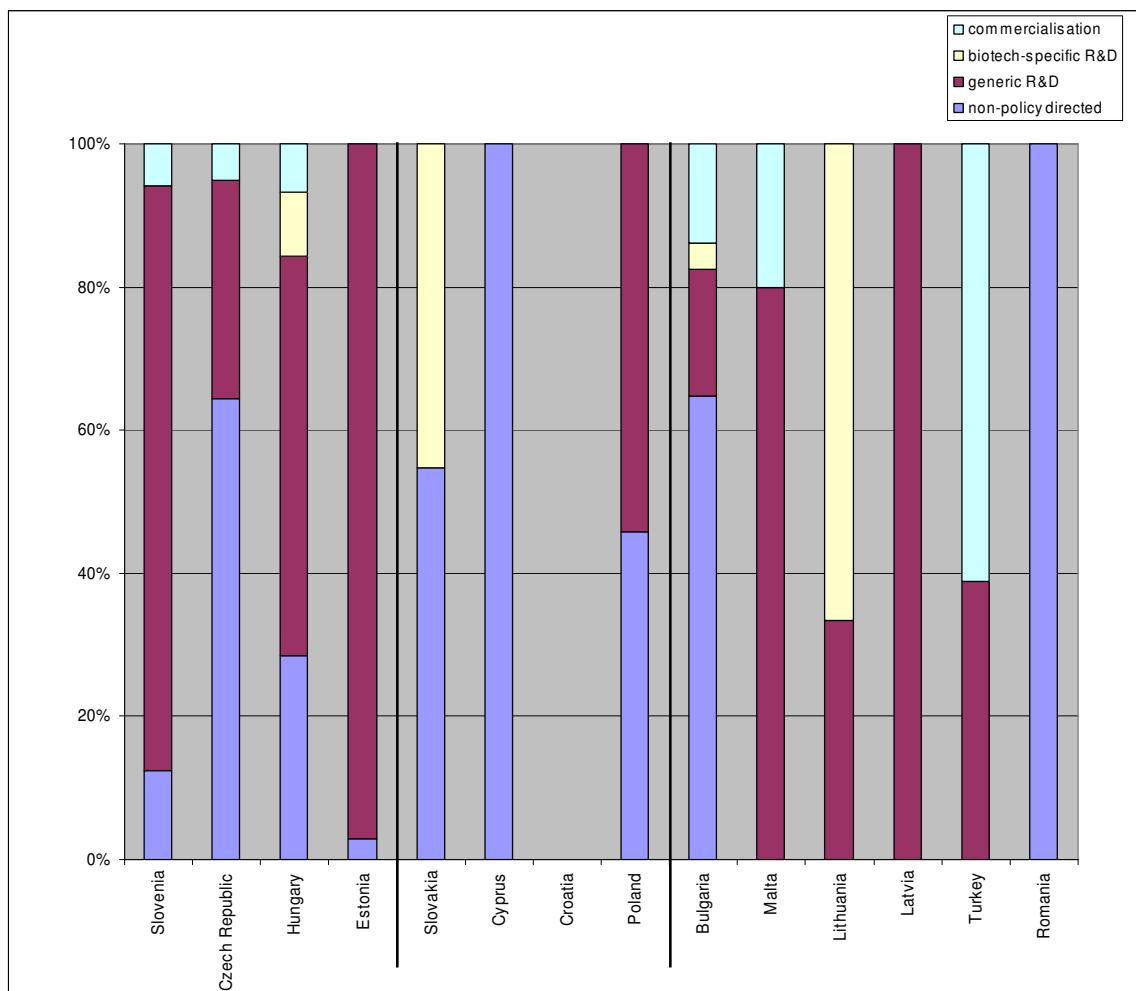
Source: BioPolis Research

### 8.3.1. Policy profiles

We conclude this section by considering features of the policy-making system for biotechnology in the NMS and AC. Figure 8.3 presents policy profiles of each country in terms of the proportion of non-policy directed and policy directed funds allocated to biotechnology. The proportion that is policy directed is broken down by the proportion allocated to promoting commercialisation as well as those for generic and biotech-specific research. It shows the persistence of non-policy directed funding in all these countries. The countries in cluster 1, except for Czech Republic, dedicate a significant proportion of funds to policy-directed instruments, including both instruments to support research and to promote commercialisation. The use of biotech-specific instruments is still infrequent.

Table 8.5 shows the number of instruments dedicated to policy-directed funding. Nine countries fund instruments to promote commercialisation, but only Bulgaria and Hungary attach this funding to biotech-specific programmes. Turkey, Hungary and Slovenia are the only countries directing funds to “other” activities (activities to promote social acceptance of biotechnology, bio-safety or risk assessment). Overall, the countries in cluster 1, the best performers, have a greater range and number of instruments than those in other clusters.

Figure 8.3 Distribution of biotech funds by method and programme type



Source: BioPolis Research

Table 8.5 Number of policy-directed research instruments by type

Country	Generic R&D	Biotech-specific R&D	Commercialisation Gen. (B-S)	Others
<i>Cluster 1</i>				
Slovenia	3	-	2	2
Czech Republic	5	-	2	-
Hungary	2	3	3(2)	1

Estonia	5	-	6	-
<i>Cluster 2</i>				
Slovakia	-	3	1	-
Cyprus	-	-	-	-
Croatia	3	-	1	-
Poland	2	-	-	-
<i>Cluster 3</i>				
Malta	3	-	1	-
Lithuania	2	2	1	-
Latvia	1	-	-	-
Bulgaria	2	1	2(1)	-
Turkey	4	-	3	1
Romania	-	-	-	-

Source: BioPolis Research

We next consider how far identification of biotechnology as a policy priority has resulted in action to develop biotechnology. Biotechnology has been identified as a research priority in every country, except Romania, Cyprus and Slovakia. However, as shown by Table 8.5 only four countries have attempted to implement this priority by allocating funds to biotech-specific research programmes – Bulgaria, Hungary, Lithuania and Slovakia.<sup>30</sup> Bulgaria and Hungary also allocate block grants to Research Institutes specialising in biotechnology. This may be due to the fact that block grants for Research Institutes or university departments focusing on biotechnology are used as the main way to implement policy in three other countries that have biotechnology as a priority: Turkey, Poland and Estonia. But neither biotech-specific programmes nor block grants for specialist public research organisations exist in five countries that regard biotechnology as a research priority: Croatia, The Czech Republic, Latvia, Malta and Slovenia. Analysis of policy implementation is further confused by the fact that three biotech-specific research programmes exist in the Slovak Republic that has not identified biotechnology as a prior-

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<sup>30</sup>Lithuania does not appear in Figure 8.6 because we were able only to gather information about the presence of instruments, but not about the amount of funds allocated to these instruments.

ity. Cyprus, for reasons mentioned at the beginning of this section, allocates block grants to a specialist research institute. These features suggest that the science and technology policy-making systems of most NMS and AC are in a process of development in terms of designing instruments that will allow them to achieve their policy objectives.

Table 8.6 presents a summary of the strategies for biotechnology that were being developed after 2005. In general, there is little specific information on specific biotechnology policies or instruments, so information is also provided on general science and technology policy trends that may affect biotechnology.

Table 8.6 Future trends in biotechnology funding

<b>Country</b>	<b>Future trends</b>
<i>Cluster 1</i>	
Slovenia	No major changes to biotechnology are expected
Czech Republic	The National Innovation Policy 2005-2010 made no reference to biotechnology
Hungary	After major reforms in 2004, no major changes are expected in the short to medium-term. Elements to improve the current policy mix could be subsidies to reverse the brain drain, especially of industrial researchers, and various support measures for start-ups, including public seed and venture capital
Estonia	It is anticipated that new biotechnology specific initiatives will be launched
<i>Cluster 2</i>	
Slovakia	Priority areas in science and technology for years 2006-2010 in development
Cyprus	No future plans regarding the specific funding of biotechnology at national level
Croatia	National Science and Technology Policy 2005-2010 adopted May 2006. Objectives include: increased investment in R&D, restructuring science system by clustering projects into integrated collaborative programmes, promoting collaboration between academia and industry, stimulating the establishment of venture capital funds. Biotechnology remains a priority, but actions to support it are not specified
Poland	The 2005 Act on Financing Science aims to concentrate expenditure on development projects that could be applied by SMEs, and to consolidate the R&D sector by promoting joint proposals. It also introduced the formation of instruments to

	support structural change, i.e. creation of science networks, consortiums and reorganization of the State Research Institutes.
<i>Cluster 3</i>	
Malta	The RTDI programme was reformed into the National Research and Innovation programme. It issued a call for proposals in 2006. Health biotech is one of the main areas of focus
Lithuania	The establishment of a biotechnology science park close to the main cluster of biotech research institutions and companies
Latvia	It is not clear whether specific biotechnology funding programmes are being developed.
Bulgaria	No major changes anticipated in the next few years. Insufficient funding for R&D will continue to be a problem. Consolidation of the large institutional research landscape will be attempted by setting thematic priorities.
Turkey	Policy may be affected by the Molecular Life Science and Technologies Foresight Project, completed 2004, which aimed to identify the most important socio-economic targets (including research, innovation, education and legal provisions) to be reached in 20 years
Romania	Policy and instruments for biotechnology remain unclear after 2006

Source: BioPolis Research

## 8.4 Performance in biotechnology

### 8.4.1 Limitations of science and technology and commercialisation Indicators for NMS and AC

To provide an appropriate context for understanding the performance data provided in this section, it is essential to discuss the limitations of using science and technology (S&T) indicators to compare the performance of the countries of Central and Eastern Europe (CEE) with OECD countries. In particular, the use of publications to assess the knowledge base and patents to assess the technology generated, have severe limitations. CEE countries have gone through an economic transformation since 1989, and have made considerable progress in harmonising their S&T statistics with OECD standards. However, these attempts are constrained by past, systemic features of the S&T activities in centrally planned economies. As these economies had a closed character, their scientists did not form part of the international science and R&D community (Radosevic and Auriol 1999). Publication of scientific results and the international communication of science were rather limited; the results of research were produced as "grey litera-

ture" and not as papers in journals. The publishing behaviour of CEE scientists changed after 1989, but the legacy of the past has affected current performance, especially in the life sciences. An analysis of CEE publications in the ISI database 1992-97 shows that post-Communist countries have a relatively homogeneous research profile with a similarly unbalanced and narrow disciplinary structure. Their internationally recognised research strengths focus around physics and chemistry, but life sciences are relatively neglected (Kozlowski et al. 1999). Two factors explain this neglect: firstly, research strengths were those linked to the military/industrial complex. Secondly, the system favoured basic and theory oriented disciplines that were less dependent on expensive equipment, but the life sciences demanded large-scale research and experimental work. This indicates that biotechnology research in CEE countries could be at an earlier stage of development than in other member states.

A second problem concerns the bias towards English language journals in publication databases. Publication indicators may omit the achievements of countries whose scientists publish in national journals because the use of English language poses a barrier, but evidence about this is anecdotal only. A recent investigation of this question did not cover CEE countries (Porter et al. 2002).

The use of patent data as a measure of technological performance also has its problems. This data is generally used to measure the performance of developed OECD economies that are at the innovation frontier. Its relevance for NMS and AC is limited by the fact that these latecomer economies are not at the world innovation frontier; they are involved in technological catching up through imitative learning. There may be very little visibility of latecomer economies in patent data during the early phases of catching up although, over time, their learning activities may lead to the development of innovation capabilities, which then become reflected in patent data (Radosevic and Kutlaca 1999).

As well as using patent data to assess commercialisation performance, the study aimed to use data on biotechnology SMEs that was comparable between countries because it had been gathered using a common definition. However, the source used for the other countries in this study (see Annex 4) does not cover NMS and AC. In addition, there was no data available on the amount of venture capital invested in biotechnology for these countries.

#### **8.4.2. Some performance indicators**

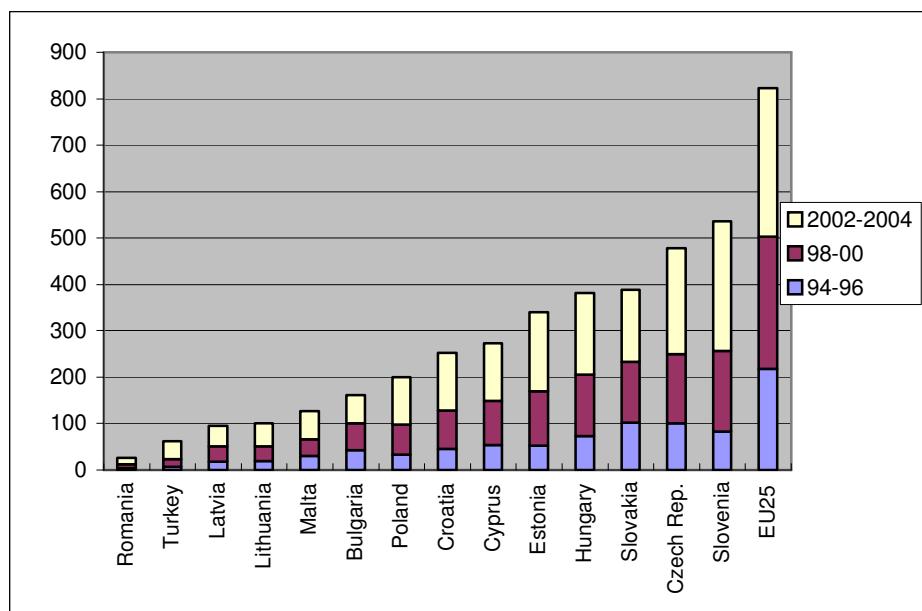
The problems with using S&T indicators to assess the performance of CEE countries made it difficult to identify clusters of NMS and AC with similar performance. Despite the limitations of publications data, it was decided that the growth in publications output over three periods, 1994-1996, 1998-2000 and 2002-2004, was the most appropriate way to identify these clusters, because significant growth in publications over time indicates that countries are building the ca-

pacity to "catch up". Publications data has been adjusted to reflect national population (per million capita: pMC) to improve comparability between countries.

Figure 8.4 shows that all NMS and AC are below the average publications output per million capita (pMC) of the EU-25, but growth in publications output over time, particularly the capacity to sustain and increase growth of publications, provides a basis to cluster countries with similar performance into three groups:

- Cluster 1: the Czech Republic, Estonia, Hungary and Slovenia are closing the gap with the EU-25.
- Cluster 2: Cyprus, Croatia, Poland and Slovakia<sup>31</sup> are making progress.
- Cluster 3: Bulgaria, Latvia, Lithuania, Malta, Romania and Turkey have weak performance.

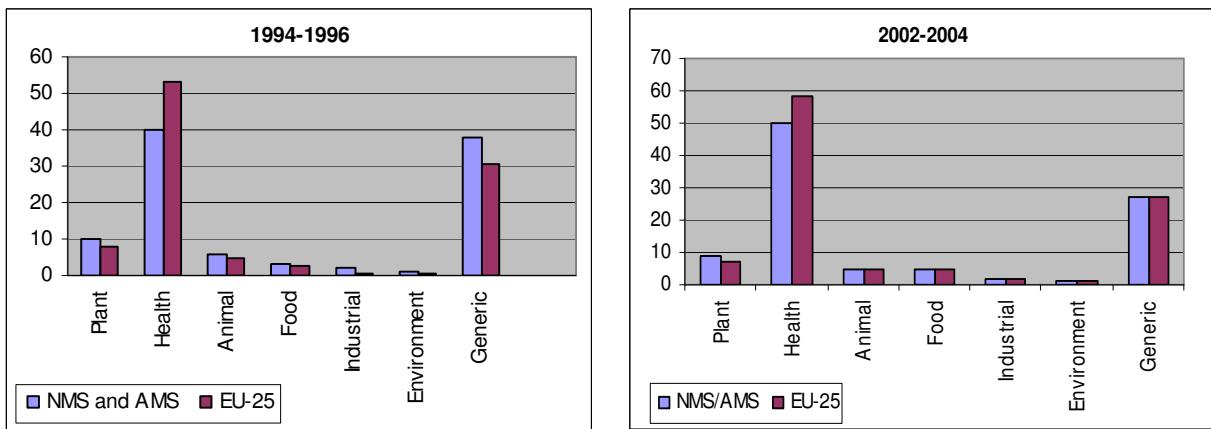
Figure 8.4 Cumulative publications pMC in New Member States and Accession Countries 1994-1996, 1998-2000 and 2002-2004



The publications output of NMS/AC was also analysed by biotechnology area over time and compared with the EU-25. As shown by Figure 8.5, in the period 1994-1996 NMS/AC had a slightly different pattern of specialisation, with fewer publications in the health area and more in plant, animal and industrial biotechnology than the EU-25.

<sup>31</sup> Slovakia is in Cluster 2 because it failed to sustain and increase its early publications output over time.

Figure 8.5 Percentage of publications by biotech area EU-25 and NMS/AMS, 1994-96 and 2002-2004



Source: BioPolis Research

However, publication patterns for 2002-2004 show that NMS/AMS have been converging toward the EU-25 pattern and not retaining their early pattern of specialisation.

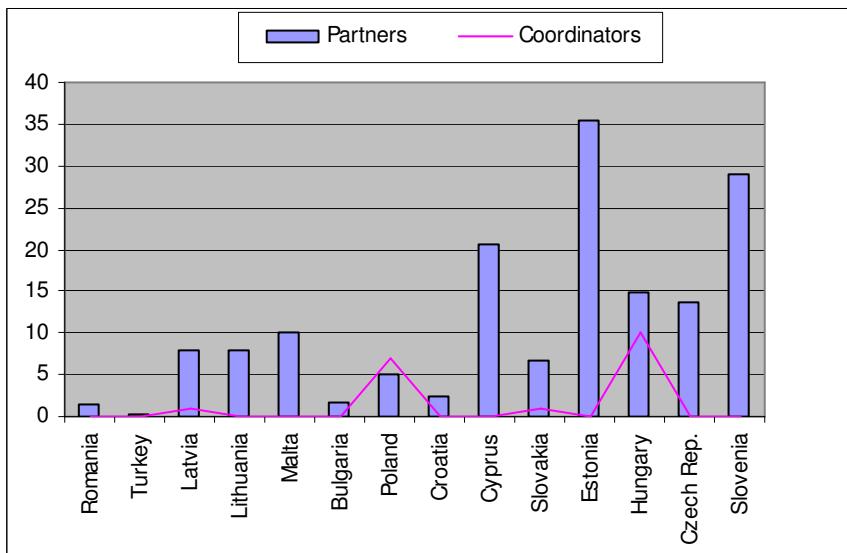
We also analysed participation per million capita of NMS and AC in three thematic priorities of the EC's Sixth Framework Programme (FP6) that covered biotechnology: (1) Life sciences, genomics and biotechnology for health; (2) the bionanotechnology section of Nanotechnologies; and (3) Food quality and safety. Participation in these programmes indicates recognition of the competence of national scientists by those from other countries. It also enables scientists in NMS and AC to learn from other partners in the programme. Figure 8.6 shows the number of project teams in which each country participated, as well as the number of projects they coordinated.<sup>32</sup>

Only a few NMS have coordinated FP6 projects: Hungary (10), Poland (7), Slovakia (1) and Latvia (1). The Slovakian and Latvian coordinators were in the Food Quality and Safety thematic priority. So were five of Poland's coordinators and three from Hungary. Coordinations may reflect these countries' strengths in food and not biotechnology.

There is limited data on commercialisation in NMS and AMS and this probably reflects the early stage of development of biotech in these countries. For instance, there is no data on venture capital investment in biotech firms or on initial public offerings (firms floated on stock markets).

<sup>32</sup> Number of coordinators has not been adjusted to national population (pMC) because absolute numbers were very small.

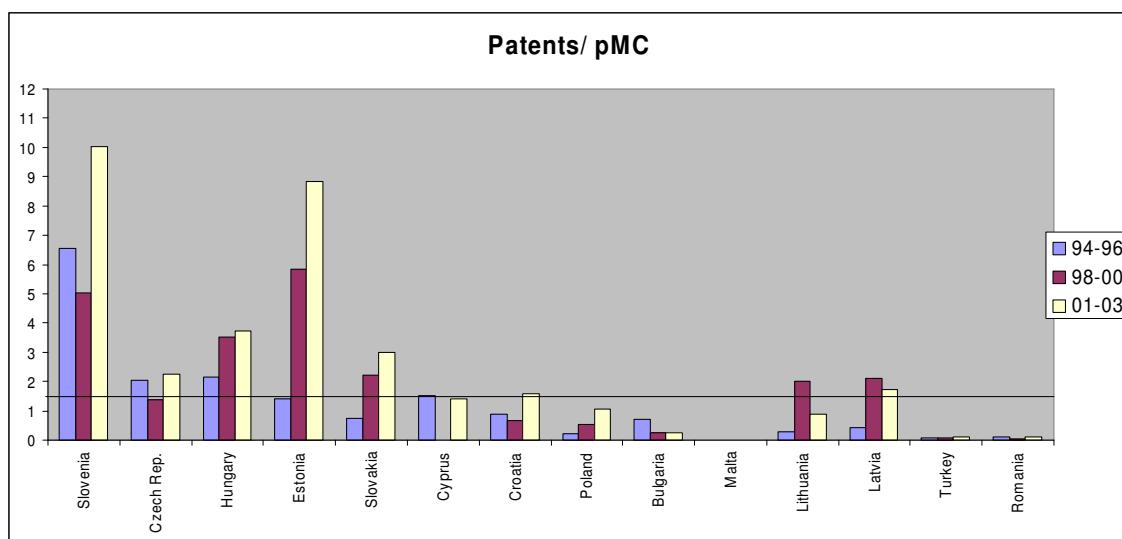
Figure 8.6 Number of partners and number of coordinators in FP6 pMC



Source: BioPolis Research

Section 8.4.1 above also discussed the limitations of technology indicators for measuring the commercialisation performance of NMS and AC. The data presented below, information on biotechnology patents and biotechnology companies for each country, must therefore be treated with great caution. Figure 8.7 shows that several countries have increased their patenting activities over time.

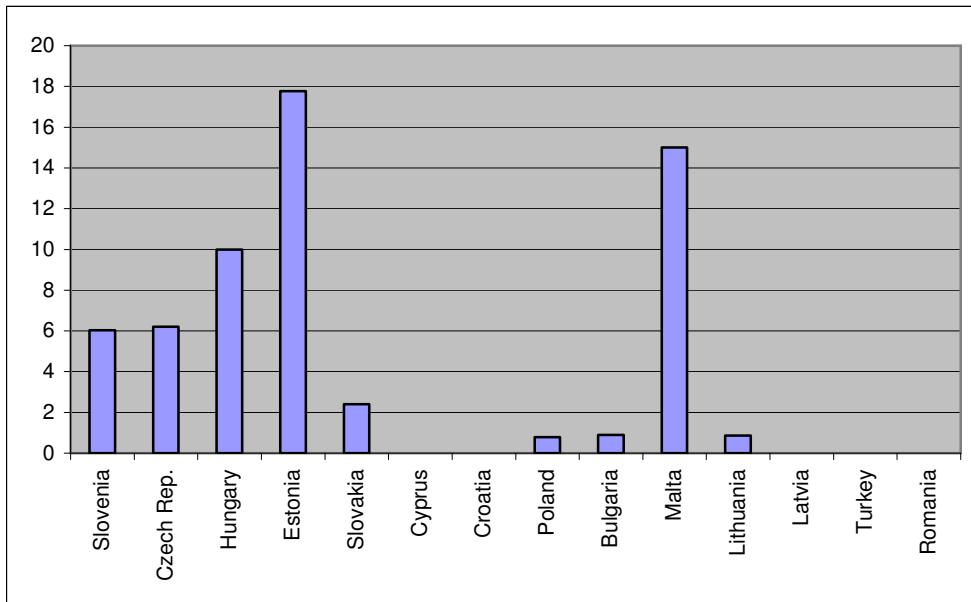
Figure 8.7 Biotech patents per Million Capita (pMC)



Source: BioPolis Research

Figure 8.8 indicates the number of biotech firms in each country, according to local estimates.<sup>33</sup> The data is not comparable because we do not know the definition used to decide which firms should be counted and it should be regarded as a very rough indication only of countries where some degree of biotech commercialisation exists.

Figure 8.8 Number of biotech companies per Million Capita (pMC)



Source: BioPolis Research

## 8.5 Policy characteristics supporting biotechnology development

The limited information available for some of the NMS and AC, and the problems with using STI indicators to assess national performance, makes it difficult to draw strong conclusions about the policy characteristics supporting the development of biotechnology in these countries. However, it is clear that the history and traditions of each country can have a negative or positive impact on performance. For instance, CEE countries have had to overcome many barriers that hindered the development of biotechnology capabilities. They have had overcome the neglect of the life sciences under communism and the former science system in which research was mainly carried out in Academy of Science institutes with universities involved only in education. For biotechnology, in particular, where strong links between public sector research and industry have been and remain crucial to the commercialisation of biotechnology, the historic separation

<sup>33</sup> More than one estimate existed for some countries and sometimes the figures differed enormously. We have used the lower estimate in each case.

between academic research and industry has also been a major problem. Some, but not all CEE countries have made progress in solving these problems.

On the other hand, previous history can have a positive impact on national performance in biotechnology. It appears that the existence of pharmaceutical companies in a country can be beneficial, especially when the companies conduct research and are involved in science policy advisory bodies.<sup>34</sup> Similarly, the scientific capabilities of Cyprus in health biotechnology have benefited from a 45 year history of government support for research to control a widespread, inherited genetic disorder affecting its population.

Government science and technology policy is a significant factor that can often explain the biotechnology performance of the three clusters of countries. However, clustering is based on publications performance in 2004, which resulted largely from the policy system in place around the turn of the century and not from the current policy systems in the 14 countries, which have been evolving rapidly over the past few years. However, we conjecture that Cluster 1 countries, the “catching up countries”, have been quicker to adopt policy approaches recognised as supporting the development of biotechnology in the old member states but usually absent from weak countries or those making slow progress (Clusters 2 and 3) and this make explain their performance.

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<sup>34</sup> Bulgaria did not benefit in this way because economic problems during the transition period, and failure for biotechnology products to meet the demands of Western markets resulted in the allocation of insufficient resources to maintain biotechnology capabilities.



## 9. Conclusions and recommendations

This chapter summarises the main findings of BioPolis and presents recommendations for policy makers on the basis of these finding. They address all 32 countries that are covered in BioPolis, but special attention is given to the newcomers: the 12 new Member States and the two Accession Countries. The findings and recommendations will deal with the configuration of national policy making systems, performance, policy profiles and policy effectiveness and ends with specialisations patterns. Before presenting them, we present some observations concerning the methodology used in BioPolis.

### **Methodology**

A number of methodological issues are relevant to the success of a study such as BioPolis, but the most important is the availability of comparable data. Although we made an extensive Guidebook that allowed for a comparative methodological approach that was used in all country studies, for a number of countries it was not possible to provide a complete overview of instruments and funding. We are confident that the overview of biotechnology specific instruments is rather complete, and in most Old Member States and Associated Countries this also holds true for the generic instruments and the non-policy directed funding. Moreover, in these countries the comparability of data is rather high, as data collection tends to comply, for instance, to OECD guidelines. In addition, consultancy firms have collected data on high tech biotechnology firms for many years.

However, the availability and comparability of such data was rather poor in most of the new Member States and Accession Countries. It was very difficult to locate the relevant persons in government and funding organisations that could provide us with the information we needed. Once found they were mostly very willing to cooperate, but some of these contacts did not respond. One of the reasons might be that some countries lack of a tradition for collecting and presenting data on instruments and funds for specific technology fields. This implies that the data presented in some national case studies and this Final Report are underestimates of the biotechnology funding in those countries and thus also in Europe. Furthermore, in some case rough estimates were used for some instruments.

For the performance analysis of New Member States and Accession Countries only publication data could be used, although they have to be treated with great caution as many publications are still in national languages not covered by the database used (SCI). Performance in publications and citations reflects the uptake of English and the integration into the international sci-

tific community. For New Member States and Accession Countries the number of dedicated firms is not yet collected in a comparable and systematic way.

Comparative data about the biotech activities of diversified biotech companies (number of firms, employees active in biotech; size of their biotech activities) are not available for any of the 32 countries.

Nevertheless, the overall results of BioPolis are very valuable as they provide an in-depth overview and cross country analysis of the national biotechnology policies which can be an important input to national policy learning processes and contribute to the development of more effective biotechnology policies in Europe.

### ***Recommendations***

- 1 NMS and AC should be encouraged to build up their capabilities to gather data, conforming to OECD standards where relevant, for S&T policies and budgets.

## **Configuration of the national policy making systems**

### **Coordination amongst policy actors**

Countries with convergent innovation systems – with high interactions amongst a large diversity of actors and concentrated decision making processes with *ex ante* coordination - appear to perform better than divergent ones. All weak performers have a fragmented system with low interactions between small numbers of actors, except for Portugal where a large number of actors are involved. For all countries, including the smaller ones, fragmentation of actors seems to be a weakness. Increasing coordination between different policies and between the responsible actors seems to contribute to increased policy effectiveness. It can be argued that the concentration by a few actors on the strategic decision process for biotechnology allows for a visible, stable and coherent policy-making process, leading to higher performance in biotechnology. Here smaller countries might be in a structurally better position as they have relatively less actors who know each other well.

In most of the New Member States and Accession Countries many shortcomings with the policy-making process are reported, especially the low level of coordination of government policy, the small range of actors involved in policy formulation and the creation of policy instruments to implement research priorities.

One of the strongest trends in the national biotechnology policy making systems of the old Member States is the rise in regional government participation in biotechnology policy-making. In the period 1994-98 there was significant regional policy-making for biotechnology in Member

States where the regions have responsibility for supporting university research and economic development (Germany, Belgium and Spain) and, to a lesser extent, in some regions of the UK. By 2002-2005 regions in all these countries and in Austria, France and Italy were playing a very active role in biotech policy-making; they tend to focus their efforts on research commercialisation and support to SMEs.

### ***Recommendations***

- 2 The focus of first and second generation innovation policies was on the research and education system, the business system, framework conditions, infrastructure and intermediaries. However, the systems approach of the second generation seems to have neglected the role of the government and its constituent part (the policy system). As our results show that policy coordination 'pays', it is highly recommended that national governments close the "coordination gap"; not only between national departments, but also between national and regional governments and international institutions. This involves co-ordination of simultaneous policy actions addressing the core set of innovation policies such as science, technology and education, as well as a re-direction of policy actions that pursue other primary objectives such as public health and regional development.
- 3 Particularly due to the complex nature of biotechnology innovation processes, a broad and up-to-date information base and the inclusion of different perspectives are important prerequisites for the design of successful policies. This can be achieved by enabling meaningful participation by non-government biotechnology actors – particularly representatives of the scientific community, industry, but also consumer and patient groups – in the policy process. Apart from the composition of the biotechnology policy arena, managing the processes within such a policy network warrants special attention. A higher intensity of mutual information exchanges, not only between the responsible ministries and agencies but also within a broader set of non-government actors involved in biotechnology, may help to mitigate potentially damaging conflicts within the policy network, contribute to the development of shared understanding, and eventually foster policy-learning.

### **Performance**

#### **Positive correlation between scientific and commercial performance in biotechnology**

On the basis of a combination of two performance measures (scientific and commercial) three clusters of differently performing countries have been identified. A group of four countries performs above the European median with respect to both performance measures. These include Switzerland, Denmark, Sweden and Finland.

Austria, Belgium, the Netherlands, Ireland, Norway, Germany, France and the United Kingdom belong to the second group that performs at a roughly similar level to the European median with respect to both performance types. Finally, a third cluster of countries - Italy, Greece, Spain, Portugal and Luxembourg - performs well below the European median. Iceland is a special case: due to limited data availability it is not included in the cluster analysis.

The analysis of scientific performance and commercialisation performance of the individual countries provides clear evidence of a positive correlation between scientific and commercial performance.

#### ***Recommendation***

4 Nations wishing to sustain or improve their commercial performance in biotechnology will not be successful if they focus their supporting activities only on functions of the innovation system which are directly related to commercialisation. Rather, it is important to take a holistic approach towards the system, taking care of both the scientific and the commercialisation sub-systems.

#### **Comparison of Europe with USA**

Our systematic performance analysis considers the European Union (EU15) as a whole, the individual countries (Old Member States) and the United States. Accordingly some conclusions can also be drawn by comparing Europe with the USA in terms of biotechnology performance. In general we do not find evidence that the United States plays a clear leading role.. Rather, with respect to most performance measures, the United States performs at a similar level to the best European countries. However, the position of Europe as a whole compared to the United States seems less favourable if we take into account the fact that a number of small countries have pushed the European performance score to its high level.

#### ***Recommendation***

5 Considering the great diversity in performance of European countries, it seems questionable whether it would be meaningful to compare Europe as a whole with the United States. This difficulty is enhanced by the situation in the United States where it is well known that biotechnology excellence is concentrated in few regions (such as the Boston area, North Carolina, Southern and Northern California). Such regional units might be better suited for comparison with individual European countries than the United States as a whole.

## **Policy profiles and policy effectiveness**

### **Focus on commercialisation in biotech specific instruments**

In 2002-2005 biotechnology has received increased priority in national innovation policies in the Old Members States, Iceland, Norway and Switzerland, with a rise in the funds spent on biotechnology (doubled) as well as the introduction of a large number of new biotech-specific and generic instruments since the period 1994-1998. The relative contribution of funds to biotech specific and generic instruments in total funds has scarcely changed.

Policy goals that were not covered in 1994-1998 – most dealing with commercialisation – are in 2002-2005 addressed by biotech-specific and generic instruments. This might reflect a trend in biotechnology policy making: there has been a shift of focus from science based to commercialisation based biotechnology policies. This trend to promote commercialisation was already visible in 2001 (Reiss et al. 2003), especially in countries that had a rather complete profile in terms of coverage of all policy goals by a combination of biotech specific and generic instruments. In these countries the policy profile has scarcely changed during the last ten years. The trend towards commercialisation is now also visible in countries that formerly had a more incomplete profile.

### **Successful policy profiles have a balanced mix of generic and specific instruments**

Policy profiles that include both generic and biotech-specific public policies with high importance levels and which support the science base and commercialisation activities are more successful (i.e. show higher performance levels) than countries whose policy profiles give low importance to their policies. Countries that ascribe limited importance to the creation of generic and biotech-specific instruments for the stimulation of biotechnology also perform more weakly. In other words: public policies matter.

The analysis of the effectiveness of specific science base policies seems to indicate that having only generic research stimulating instruments in place is less effective; biotech specific instruments seem to be more beneficial. However, keeping a balance between specific and generic instruments and between supporting basic and applied research seems to be important. Most highly performing countries gave equal emphasis to both areas or had some stronger focus on supporting basic research. Where support for the international mobility of researchers has been implemented, it seems to be beneficial to output. This is in particularly relevant for smaller countries that have limitations in the diversity of their domestic knowledge base. Support of the development of human resources specialised in biotechnology and regulations fostering research activities seem to make no differences in terms of performance.

The analysis of policy approaches aimed at the commercial exploitation of biotechnology indicates that all highly performing countries had generic and biotech specific instruments in place.

All the countries performing below the European average also had generic instruments but a number of these countries did not use biotech specific policy instruments. No clear conclusions could be drawn on the effectiveness of policy support measures for biotechnology research in industry or on the effect of the regulatory framework. These observations support the notion that generic exploitation approaches only are not sufficient. Rather a well balanced mix of generic and biotech specific measures seems to be superior.

### ***Recommendation***

6 It is recommended that countries implement a well balanced mix of instruments that target the creation and sustenance of a competitive biotechnology knowledge base and commercialisation. The importance of supporting commercialisation should not lead to policy profiles with an overly heavy accent on these policy goals. In countries with weak scientific performance and low research expenditure special emphasis should be given to biotech-specific policies because these are essential to building up scientific capabilities.

### **Funding systems**

Many of the New Member States and Accession Countries are undergoing significant restructuring and lack adequate public resources to invest in research in general, and in biotechnology in particular. BioPolis has found that they contributed only around 2% of total expenditure on biotechnology research of the 32 European countries covered. As mentioned before this is an underestimate, because complete information on expenditure for some countries is lacking. Nevertheless, even if the complete budget data had been gathered, their share would still remain very low.

In addition to low investment in research, BioPolis identified shortcomings in the funding systems in many of the New Member States and Accession Countries. Previous research suggests that a system where funds are allocated by research councils through a competitive, peer-reviewed process allows *ex ante* coordination, before the implementation of strategic decisions. By contrast, the funding of research through the allocation of block grants gives autonomy to organisations over the research agenda, and coordination can only be carried out *ex post*. Moreover, competitive research funding is not only flexible; it also appears to be a more effective method than direct control of funds by research institutions to achieve a strong international orientation and higher scientific performance (Reiss et al. 2003). In many New Member States a high proportion of research funding is also allocated as block grants to universities and/or institutes.

***Recommendation***

- 7 Research performance of New Member States and Accession Countries would benefit by taking steps to move away from a research system principally based on the allocation of block grants. The quality and relevance of research is likely to be enhanced by greater use of competitive, peer-reviewed research grants. However, block grants may be allocated to public research centres dedicated to a specific area of research, e.g. molecular biology, with continued funding being dependent on the outcome of regular evaluations of performance (as is the case in some Old Member States).

**Specialisation**

We observed more or less the same national specialisation patterns in biotechnology throughout Europe. The overall specialisation pattern of the 15 Old Member States, Iceland, Norway and Switzerland did not change very much: red biotech (health) is by far still the most important, followed by green biotech (agrofood: about one third of the health budget) and finally white biotech (industrial and environmental biotech). However, the position of white biotech improved as its relative contribution rose from 11% to 16%, at the expense of red and green biotech. The high focus on red biotech was even more strongly visible in the publication output.

The New Member States and Accession Countries had in the period 1994-1996 a slightly different pattern of specialisation, with fewer publications in the health area and more in plant, animal and industrial biotechnology than the EU25. However, publication patterns for 2002-2004 show that these countries have been converging toward the EU25 pattern and not retaining their early pattern of specialisation.

***Recommendation***

- 8 The observed lack of variety in focus on specific biotechnology application areas among European countries raises the question of the current status of a European research area in this field. Obviously, such a construct seems far away from being realised at present. Considering the differing industrial orientations of European countries and, accordingly, the differing opportunities for the industrial adoption of biotechnology, it does not seem to be advisable for the different countries to strive to achieve similar specialisation goals in biotechnology. This would lead to a uniform European research area that did not take advantage of national strengths. A system combining various national specialisations based on different national industrial strengths would be more competitive.

BioPolis provides the first in-depth overview of the biotechnology policy making systems and policies of the twelve New Member States and two Accession Countries. These countries are

mainly latecomers to the development and exploitation of biotechnology. They are correct to develop capability in this significant technology which has a rapidly expanding knowledge base. Without such capability they will lack the competence to absorb and utilise the knowledge which is being created in the rest of the world.

For New Member States and Accession Countries there is a danger that in attempting to secure benefit from their investments in public biotechnology research these countries will focus on exploiting the potentially high value-added, pharmaceutical applications of biotechnology. If they follow this strategy, however, they are unlikely to succeed, as the competition is too strong. In addition - and this applies also to Old Member States - there is need for capabilities in myriad new platform technologies: rational drug design, combinatorial chemistry, screening, bio-informatics, DNA sequencing, gene expression, pharmacogenomics and proteomics. Building up an adequate knowledge base in even one of these areas requires very large research teams, and it would be unwise for New member States and Accession Countries to concentrate limited resources for biotechnology on a few research areas only.

***Recommendation***

- 9 New Member States and Accession Countries are more likely to succeed if they support biotechnology research that is relevant to strong economic sectors within their countries. There are some older Member States that provide examples of how to do this. They are building up competence in niche areas of biotechnology where they have the potential to achieve competitive advantage. For instance, Norway has applied biotechnology to its strong marine research sector, concentrating on the health of fish and fish feed. Denmark has programmes improve the use of biotechnology in food research. Germany and the Netherlands put strong efforts in developing industrial biotechnology as its application to their chemicals sectors can increase companies' competitiveness by reducing costs, increasing profits and reducing pollution.

## Annex 1

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## **Websites**

Eurostat: <http://epp.eurostat.ec.europa.eu/>

## Annex 2

### List-based definition of biotechnology

Biotechnologies		
<b>DNA / RNA</b>	Antisense	Gene mapping
	Chemical genetics	Genetic engineering
	Chemical genomics	Gene expression analysis
	DNA amplification	Gene function analysis
	DNA hybridisation	Genetic fingerprinting
	DNA library	Genetic screening
	DNA polymerase	Genomics
	DNA/RNA micro arrays	Structural genomics
	DNA sequencing	Pharmacogenetics/-omics
	DNA synthesis	Recombination / recombinant DNA
	Functional genomics	Restriction fragment length polymorphism
	Gene/DNA probes	
<b>Proteins and other molecules</b>	Cell receptor	Molecular biotyping
	Cell signalling	Molecular modelling
	Chiral synthesis	NMR spectroscopy
	Combinatorial chemistry	Peptide sequencing
	Diagnostics test & antibiotics	Peptide synthesis

	Electrophoresis	Protein arrays, protein libraries
	High throughput screening	Protein (glycol) engineering
	Improved delivery methods for large molecule drugs (use of glycol and lipid chemistry, etc)	Protein sequencing
	Immunodiagnostics	Protein synthesis
	Lipid (glycol)engineering	Proteomics
	Mass spectroscopy	Radioimmunoassay
	Metabolic engineering	
<b>Cell and tissue culture and engineering</b>	Cell culture	Micro propagation
	Cell handling	Monoclonal antibodies
	Cellular fusion	Protoplast fusion
	Cloning	Tissue culture
	Embryo manipulation	Tissue engineering
	Hybridisation	Viral vectors
	Micromanipulation	Xenotransplantation
<b>Process biotechnology techniques</b>	Bioaugmentation	Bioreactors
	Biobleaching	Bioremediation / Phytoremediation
	Biocatalysis	Bioprocessing
	Biodegradation	Biopulping

	Biodesulphurisation	Biotransformation
	Bioenrichment	Enzyme technology
	Biofiltration	Fermentation using bioreactos
	Bioleaching	
<b>Bioinformatics</b>	Computational biology	Modelling complex biological processes
	Databases on genomes, protein sequences	Systems biology
<b>Nanobiotechnology</b>	Tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics etc.	

Sources: the list-based definition of the OECD (2004), the list of biotechnologies of the US Department of Commerce (2002) and the list provided in the EBIS-project (Senker et al. 2001).

## Annex 3

### Categorisation of actors

The categorisation of actors in the national biotechnology innovation system in BioPolis is based on the categorization introduced in the Inventory project (Enzing et al. 1999) that was also used in the Epohtite project (Reiss et al. 2003).

The key players in the national governance and funding system are:

1. National government bodies:

- Ministries of education, science, research (or similar, some also have responsibilities in additional fields)
- Ministries of economy, industry, trade (or similar, some also have responsibilities in additional fields)
- Sectoral ministries (agriculture, public health, environment)

Governments can have a separate body in charge of science and technology policy, which coordinates the policy on science, technology and/or innovation across the government (e.g. Office of Science and Innovation in the UK or the Office for Scientific, Technical and Cultural Affairs in Belgium).

2. Regional government bodies:

- Regional ministries

3. Advisory organisations:

- National science and technology advisory boards
- National innovation advisory boards
- National high tech industry advisory bodies
- National Bio-ethics advisory bodies

Advisory boards often include the interests of stakeholders in their decision making, including those of patients and consumer organisations, environmental groups and other NGOs and social issue groups.

4. Public funding organisations of research<sup>35</sup>:

- Research councils
- Funding agencies
- Charities

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<sup>35</sup> In the Inventory these funding organisations were referred to as 'Intermediary actors'

The implementation of research and innovation policies can be managed by specific funding organisations. These organisations can be linked to a specific ministry, but can also manage programmes that are supported by several ministries. The funding organisations are the service desk to the research actors; they provide information, organise the application and selection process, and provide the grants to successful applicants, etc. The research councils are one type of funding organisation. They mainly focus on basic research and are open for applications mainly by university research groups. They operate in a response mode where only peers are involved in the selection process and in some countries they also fund research in their own sponsored institutes through block grants. In other countries they also support applied research, with involvement of industry in the formation of the programs and in the selection of projects.

Charities and foundations are private initiatives that aim to support a specific group or issue in society. Especially in health care, charities and foundations also support research activities in specific research fields. Their support is channelled through direct research support through response mode and/or in the form of block grants to certain research groups. Some charities even run their own research institutes.

In addition, ministries of education, research, science, ministries of economy, industry, trade and sectoral ministries provide funding to national research actors (public and private) in a variety of modes including lump sum funding for universities or to their research institutes and in a competitive mode through specific programs which they manage themselves.

5. The main actors in the national biotechnology R&D infrastructure include:

- Public Research Organisations;
- Companies.

Public Research Organisations are organisations performing research for which the main source of funds is other public organisations which are in public ownership or control. This includes research groups of universities, academic hospitals and of public research institutes. Research organisations of officially recognised charities or foundations, which raise the majority of their funds from the general public, are also considered as public funding organisations.

In biotechnology a distinction is made between so-called dedicated biotechnology companies and diversified biotechnology companies (OECD 2004). Dedicated biotechnology companies are high tech companies specialised in biotechnology. They are active in R&D and the application of biotechnology in processes/ products and services. Their core areas fall within at least one of the biotechnology areas mentioned in 2.3.1. and which apply one or more of the technologies mentioned. Most dedicated companies are rather small; some have grown into medium-sized or even large firms. Diversified biotechnology companies have developed also technological competences in other fields than biotechnology. They may do R&D in biotechnology, but can also use biotechnology developments developed by others. Their role is to commercial-

ise new knowledge of biotechnology, embodied in products. Most diversified companies are large national or multinational enterprises.

Companies can also fund research in public research organisations; through participation in a public program or in a specific project or through contract research.

## Annex 4

### Performance Indicators, Comments and Time periods

No	Indicator	Comments	Time periods
1	Biotech publication per million capita (pMC)	Index: Reference Region EU25 =100 and US data for comparison	(1) 1994-1996, (2) 1998-2000, (3) 2002-200
2	Biotech publications per BT public R&D expenditure	Only for those countries in the inventory Index: Reference Region EU25 =100	BT Pub 2002-2004 / Total Pub Expenditure 1994-1998 MEcu
3	BT Patents / BT Publication	Index: Reference Region EU25 =100 and US data for comparison	(1) 1994-1996 (2) 1998-2000 (3) 2001-2003
4	BT Publications/ Total pub	Index: Reference Region EU25 =100 and US data for comparison	(1) 1994-1996 (2) 1998-2000 (3) 2002-2004
5	Citations to BT publications	Index: Reference Region EU25 =100 and US data for comparison Small country effect	(1) 1994-1998 (3) 2000-2004
6	Graduates in life sciences pMC	Index: Reference Region EU17 =100 and US data for comparison	(2) 1998 (3) 2002
7	BT Pub in Subfields in % of total BT	Data in % EU25 and US data for comparison	1994-1996 2002-2004
8	BT Pub in subfields growth rates (period 3 – period 1) /period 1	EU25 and US data for comparison Small field effect	Growth rate between 1994/ 96 (period 1) and 2002/ 04 (period 3)
9	Biotech patent applications pMC	EU25 and US data for comparison	(1) 1994-1996 (2) 1998-2000 (3) 2001-2003
10	Number of biotechnology companies pMC	Europe (data available) and US data for comparison	(2) 2001 (3) 2004
11	Number of Biotech Start-ups pMC	Europe (data available) and US data for comparison	(3) 2001-2003 (only one period)

No	Indicator	Comments	Time periods
12	Number of Biotech IPOs pMC	Europe (data available) and US data for comparison	(2) 2002 (3) 2005
13	Venture Capital in € pC	Europe (data available) and US data for comparison	(2) 2002 (3) 2004
14	BT Acceptance Index	Source: BT Policy Benchmarking 2005 The biotechnology acceptance index is a composite index and draws on the questions Q.12, Q.13.1 and Q14.01 and Q14.09 of the Eurobarometer 58.0	2002
15	Eurobarometer 225	See section 3.3 and sections 3.4.1, 3.4.2, and 3.4.3 of the Special Eurobarometer 225 <sup>36</sup>	2005
16	Biomedicines	Source: BT Policy Benchmarking 2005 Index: Reference Region EU15 =100 US data for comparison	1995-2002
17	Field trials	Source: Biotechnology Innovation Scoreboard 2002 Index: Reference Region EU15 =100 US data for comparison	1996-2001

The following methodological issues are related to some of the indicators:

- Patent BT / Publications BT (indicator no 3) replaces the indicator BT publications basic research/ BT publications applied research. Results of the EPOHITE project have shown that the original indicator does not differ significantly in the case of old EU member states. This might be the result of methodological problems associated with the indicator, since the definition of basic and applied research is based on a journal classification made by SCI. The explanatory power of this indicator is therefore questionable.
- To calculate the citation rate (indicator 5) first the publications for the period 1994-1996 (set 1) were searched and all the publications in 1994-1998 that cited any publications in set 1 (set 2). Citation rate has been calculated by (number of publications in set 2) / (number of publications in set 1). However, many of the articles in set 2 cited not only one article in set 1 and these duplicated citations are not taken into account in our calculation. For example, if there are 2 articles in set 1 and they each has one citation but cited by the same article, there is only 1 arti-

<sup>36</sup> [http://europa.eu.int/comm/public\\_opinion/archives/ebs/ebs\\_225\\_report\\_en.pdf](http://europa.eu.int/comm/public_opinion/archives/ebs/ebs_225_report_en.pdf)

cle in set 2. The citation rate for the 2 articles in set 1 is 0.5 instead of 1. This depreciation is more obvious in countries with more publications such as USA and EU25 since the possibility to cite multiple articles in set 1 is large. Accordingly the citation rates of USA and EU25 are a bit underestimated.

- The indicator 'Citations to BT publications' (no 5) seems to have a 'small country effect' bias. Small countries show a relatively large citation rate. A possible explanation might be that, as far as number of publications is concerned, larger countries usually have a larger 'middle quality' share of research results (in terms of impact) while smaller countries usually have a 'low in number but good in quality' publications impact. This can be explained by the concentration of resources allocated to selected research groups in small countries. Small countries may concentrate resources in outstanding research units. Accordingly, fewer publications may have greater impact.
- The EU25=100 index is applicable in the indicator 'Graduates in life sciences pMC' (indicator no 6) since data was only available for 17 member states.
- For those countries starting from zero in period 1 (1994/1996), the growth rate of BT publications in subfields (indicator no 8) was set to 100% if the number of publications in period 3 (2002-2004) was larger than zero. On the other hand, if the country reduced the number of publications to zero in the period 2002-2004, the growth rate was -100%. Given that a relative growth rate was used, small fields tended to have relatively larger growth rates.

To benchmark each country we chose EU25 (or EU15 if data was not fully available) as the reference region. In those cases where data for EU25 or EU15 were not available, the reference corresponds to the sum of national data available. Moreover, to ease the presentation of indicators with different scales in a given chart, an index value was used.

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