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Benchmarking of public biotechnology policy

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Introduction and objectives

Biotechnology has a high priority on the political agenda of the Member States of the European Union. However, designing policy to foster innovation in biotechnology is not an easy task, because biotechnology is a complex field with complex potential outcomes and impacts. The policy-making process faces a number of challenges: In order to assess the effectiveness of various policies it is necessary to describe and assess the specificities and functions of the national biotechnology innovation systems and relate them to specific policy areas and policy goals. Assessing national strengths and weaknesses relies on the availability of suitable indicators. Finally, policy instruments need to be adapted to the stage of the industry life cycle in each country and to the global evolution of the industry. With respect to all these issues, at present only partial information is available. Therefore, so far no systematic approach for benchmarking public biotechnology policy has been made. In line with the Communication of the European Commission "Life sciences and biotechnology – A strategy for Europe" (action 12), this project tries to fill this gap and provides firstly a conceptual and methodological basis for benchmarking public biotechnology policy, and secondly performs the first implementation round of the benchmarking in European Member States.

The benchmarking concept

The benchmarking concept combines the portfolio of national biotechnology policies with the national performance in biotechnology. Three key aspects are considered in this context:

(1) the systemic nature of the innovation process in biotechnology;

(2) the different policy areas involved in its promotion; and

(3) the time lag between policy action and potential policy outcomes.

Four broad sub-areas of biotechnology innovation systems were identified as targets for potential policy intervention:

(1) the generation and maintenance of a suitable knowledge base for biotechnology and the availability of qualified human resources;

(2) the transmission of biotechnological knowledge from the sites of its generation to possible loci of application;

(3) the full integration of biotechnology into economic sectors via the successful introduction of biotechnology-based products into the markets;

(4) the industrial development of the biotechnology sector including small and medium-sized enterprises and larger firms.

Within these four subsystems, altogether 14 goals for policy action were identified. The policy goals were assigned to seven policy areas (education, research, exploitation, industrial development, fiscal, regulation, demand) which basically cover the whole range of possible policy portfolios within the policy-making system. For assessing the achievement of policy goals, a set of 13 output indicators based on scientific publications and citations, number of PhD graduates, patent applications and number biotechnology firms, responses to the Eurobarometer survey, drug approvals, number of field trials with GMO, size of industrial sectors relevant for the application of biotechnology, number of initial public offerings, number of public biotechnology firms, and venture capital invested into biotechnology was developed.

Implementation of the benchmarking concept

In order to map national policy portfolios with relevance for biotechnology a policy questionnaire for policy-makers was developed which contains a set of core questions covering the basic information required for elaborating and monitoring biotechnology policy profiles. Some additional questions on policy issues of specific interest, such as the implementation of EC directives at the national level, were included. In order to capture the achievement of policy goals, data for the output indicators were collected by the project team. Due to the time lag between policy activity and potential policy effects, output indicators are only able to assess the achievement of policy goals set in previous years.

The approach to benchmarking was validated by using historical data (1994–2002) on policy activities and national performance in biotechnology. The historical analysis provided a proof of concept of the benchmarking approach and showed that it is feasible to elaborate the proposed policy input factors on a country level via the policy questionnaire and that the suggested output indicators provide meaningful information on the achievement of certain policy goals set in the past. In order to facilitate the transfer of the benchmarking concept to interested Member States, various information measures (written information on the benchmarking concept, presentation of the concept at different meetings, explanations in bilateral discussions with policy-makers, inclusion of national experts in some of the new Member States) were taken. Finally, 21 Member States (14 old Member States, seven new Member States) agreed to participate in the first round of benchmarking and provided data to analyse their biotechnology policies in the year 2004.

Benchmarking results across European Member States

A comparison of the national policy portfolios between countries and between the different periods considered indicates a reinforcement of public policies in favour of biotechnology in recent years. Policies supporting research and education are in place in most countries. In addition, some countries have implemented initiatives to support business courses in university degrees in biotechnology. Most countries foster the exploitation of public biotechnology research via the stimulation of entrepreneurship, spin-offs and collaborative biotechnology research between industry and public sector research organisations. Policy instruments to support industrial development are related mainly to improving the availability of financial capital and various forms of business support for start-ups. Policies aiming at creating biotechnology clusters are less favoured policy instruments.

The analysis of the development over time of the policy profiles indicates that, in addition to direct interventions, the provision of a favourable environment for biotechnology is gaining importance. Policy instruments for that purpose include fiscal policies which have become widespread in old Member States, regulatory approaches and also demand-oriented policy activities, comprising for example initiatives for exploring the benefits, costs and risks of the application of biotechnology. However, this trend towards paying more attention to the demand side is restricted mainly to the old Member States.

In general, the comparison between old and new Member States indicates that the policy portfolios of the new Member States are less comprehensive and more patchy. Most new Member States focus on education, research and exploitation policies. Industrial development and creating favourable framework conditions for biotechnology are considered only in few new Member States.

The analysis of policy-making processes reveals that dedicated instruments for policy coordination and policy impact assessment are not widespread in the European Member States.

The comparison between the performance of countries in biotechnology and the respective policy settings allows discussing the effectiveness of various policy approaches. In this context it is important to consider the time lag between policy activity and potential outcomes of any policy measures. Accordingly, the following discussion relates to policies of the mid 1990s and performance in 2002. In addition, it should be noted that simple correlations between policy input and national performance are not adequate, because policy is only one among several factors having an impact on performance.

The analysis of policies fostering the knowledge base for biotechnology indicates that a strong financial commitment to supporting biotechnology is an important but not sufficient precondition for effective policies. Another important factor is the relation between biotechnology-specific and generic policies. Having in place specific policies for biotechnology pays off in early stages of the sector as was the case in Europe during the mid 1990s. Sweden, Denmark, the United Kingdom and Belgium present examples for such approaches. In addition, most well-performing countries such as the Netherlands, Belgium, Germany, the USA and Canada gave equal emphasis to policies supporting basic research and policies supporting applied research. Finally, the supportive function of regulations is an additional asset when building up a good knowledge base as shown by the examples of Sweden and the Netherlands.

The evaluation of policies supporting knowledge transmission firstly indicates that having only generic exploitation policies is not sufficient. Well-performing countries (e. g. Denmark, Sweden, Finland, Belgium, and the Netherlands) have implemented a mix of generic and biotechnology-specific measures. When designing policies to support infrastructures for biotechnology it pays off to combine such measures with support of service functions. For example, the experience made by Ireland, Sweden, Finland, Denmark, the USA and Canada indicates that the effects of infrastructural measures can be enhanced considerably if service functions such as advice on patenting, management, financing and regulatory issues are added. In particular in the USA creating supportive framework conditions for exploitations had a higher priority compared to European countries. These relate in particular to patenting in general and at universities, company creation, access to private capital and hiring foreign staff. Fiscal instruments gave additional support for exploitation in the USA.

In order to improve social acceptance of biotechnology, comprehensive policy approaches which include a broad variety of different measures (technology assessment, foresight, workshops, and infrastructure) as was the case in Denmark and the Netherlands are most efficient.

Concerning policies to improve market access for biotechnologies most well-performing countries had fiscal instruments in place during the mid 1990s which aimed at supporting innovative activities of large firms. Such a policy approach contributes to generating a large domestic “technology market”, where large firms demand technologies and services provided by biotechnology companies.

Assessment of the benchmarking process and recommendations for improvement

Altogether, the participating policy-makers of old and new Member States were very positive about the benchmarking. The policy questionnaire was considered as a useful instrument for retrieving information and enhancing awareness. New Member States considered the policy questionnaire as a very helpful feedback on the domestic policy design process. The experience with the first round of benchmarking showed that gathering the policy input information using the questionnaire works well in a decentralised way. Concerning the output indicators, the participants argued that a central procedure for gathering such information would be highly appreciated and would not only improve but even form a prerequisite for having available comparable output data. The key recommendation made by the participating countries is that the benchmarking, and in particular the policy survey, should be repeated in the future in order to become fully exploitable and useful.

The benchmarking approach also has some limitations. In particular, the collected policy profiles can be considered just as starting point for a more detailed policy analysis which provides in-depth information on specific policy instruments. For this reason and also in order to elucidate the relationship between policies and impact in more detail two case studies were performed within this project. The first case study provides an in-depth analysis of best practice technology transfer. The second case study gives an overview of policy approaches in Europe to support biotechnology adoption by established companies.

In summary, the experience with this first round of benchmarking has shown that the benchmarking concept provides suitable tools for assessing national policy portfolios. In addition, the elaborated output indicators provide meaningful measures for assessing possible effects of policy actions taken in previous years. However, at present the quality, coverage and availability of some basic output indicators is weak due to lacking internationally comparable biotechnology statistics. In order to take full advantage of the benchmarking process, it is necessary to detect dynamic changes in the evolution of policy activities on a national and on a European level. For that purpose it is important to repeat the benchmarking periodically. We recommend to consider intervals of two to three years between two benchmarking rounds. As long as harmonised basic statistical data on biotechnology is not available, it is recommended to collect output indicators centrally, following the instructions summarised in the benchmarking manual. Policy input information, on the other hand, can be gathered locally by interested policy-makers based on the manual and the policy questionnaire.

1 Introduction and objectives

Biotechnology is widely considered as a major contributor to economic growth in various industries. Furthermore, biotechnology is perceived to create major impacts on the quality of life by affecting health care, nutrition and the environment (European Commission 2002, European Commission 2003). Therefore, as has been shown by a number of recent EC-funded research projects (INVENTORY, EBIS, EPOHITE[1]), in the fifteen old Member States biotechnology has a high priority on the political agenda (Enzing et al. 1999, Senker et al. 2001, Reiss et al. 2003). And also in several new Member States there are various efforts to develop biotechnology (see e. g. the recent detailed analysis of the state of biotechnology in Estonia by Menrad et al. 2003).

However, designing policy to foster innovation in biotechnology is not an easy task because biotechnology is a complex field with complex potential outcomes and impacts. For example, the science base of biotechnology draws on various disciplines, many diverse actors generate knowledge, and the interaction between these actors is considered as a key driving force for knowledge generation. Technology transfer from science to industry depends on the availability of expertise in biotechnology, business issues and intellectual properties rights (IPRs). Thus, education, research and innovation policy need to implement a mix of various instruments that support best this complex knowledge-generating process, taking into account increasingly limited resources. In addition, safety and ethical issues of biotechnology call for policies to create framework conditions that facilitate the development and utilisation of biotechnology in a responsible and sustainable way. Finally, the materialisation of biotechnology will take place in various different sectors which at least partly are characterised each by their very specific socio-economic features.

For example, already today biotechnology has important impacts on the health care sector by providing new tools for elucidating the causal relationships, underlying diseases or providing new approaches towards the development of drugs (Reiss 2001). The health care sector is a high-tech sector characterised by high R&D intensity, strong international orientation, multinational firms as well as medium-sized and small high-tech firms. The agro-food sector on the other hand, where biotechnology is expected to have major impact on plant or animal production or food processing, is a typical low R&D intensive sector with strong traditional and also cultural roots, depending on regional or local characteristics and conditions.

1 The results of the EPOHITE project have been published as a special issue of *Science and Public Policy*, vol.31, no. 5, October 2004.

These characteristics of biotechnology imply that the policy-making process in this area faces a number of challenges:

- Policy-makers need to identify the policy areas (e. g. research, education, fiscal regulation policy) that are most relevant for the development of biotechnology considering their specific national context.
- In the policy areas identified specific policy goals need to be defined.
- In order to assess the effectiveness of various policies, it is necessary to describe and assess the specificities and functions of the national biotechnology innovation system (see Senker et al. 2001) and relate them to specific policy goals.
- This in turn requires information on the performance of the respective national biotechnology innovation systems.
- In order to assess performance and to identify strengths and weaknesses, reliable tools are needed.
- Policy instruments need to be adapted to the stage of the industry life cycle in each country and to the global evolution of the industry.

With respect to all these issues at present only partial information is available and so far no systematic approach for benchmarking public biotechnology policy had been made. This project tries to fill this gap and provides firstly a conceptual and methodological basis for benchmarking public biotechnology policies, and secondly performs a first implementation round of the benchmarking activity. Thereby the project is directly related to the Communication of the European Commission “Life sciences and biotechnology – A strategy for Europe” (European Commission 2002) where action 12 announces that “the commission will also establish with Member States a programme for benchmarking relevant elements of biotechnology policies, in addition to existing benchmarking structures”.

Further, the project is related to action 10 of the EU life sciences strategy, where the establishment of “a contact network with Member States’ ministries with responsibility for competitiveness in biotechnology” is described (European Commission 2003). The role of this network (referred to as “Commission Biotech Network” in this report) in this particular project was to develop together with the project team the benchmarking project and to participate in the first round of benchmarking.

Against this background, the general aim of the project is to provide European policy-makers with a set of tools that will assist them in their policy-making regarding biotechnology.

In specific, the benchmarking project delivers the following:

(1) tools to map national policy portfolios;

(2) tools that facilitate monitoring of dynamic changes of policy portfolios;

(3) a set of output indicators reporting the achievement of certain policy goals set in previous years.

The benchmarking concept aims at an *internal* benchmarking at the country level. Iterating the exercise in regular intervals will allow monitoring the development of policy portfolios over time. In addition, as an optional outcome the positioning of individual countries in relation to the European situation will be possible resulting in a comparative benchmarking.

This report is organised as follows: The core part of the report starts with the description of the benchmarking concept (chapter 2) and its implementation (chapter 3). Following is a summary of the results of the first round of the benchmarking exercise in European Member States (chapter 4). Finally, an assessment of the benchmarking process is given including recommendations for future improvement of this exercise (chapter 5).

All detailed results of the project are summarised in the annex. Annex 1 contains the definitions used in the project, annex 2 gives a detailed description of policies and policy goals used in the framework of the benchmarking. Annex 3 presents the methods used for benchmarking including a questionnaire to collect information on policy portfolios from the Member States, the methods to analyse the questionnaire, and information sources and the elaboration of output indicators. A fourth section of the annex presents a detailed description of national policy profiles of all participating Member States and the USA and Canada. Annex 5 summarises the output indicators collected during the project. Finally, two case studies carried out within the project are shown in annexes 6 and 7.

In addition to this report all details of the methodology which are required to carry out policy benchmarking are described in a separate document – the benchmarking manual for policy-makers.

2 The benchmarking concept

The benchmarking concept aims at integrating the portfolio of national biotechnology policies and the national performance in the development and commercialisation of biotechnology. This integration considers three key aspects: (i) The systemic nature of the innovation process in biotechnology; (ii) the different policy areas involved in its promotion; and (iii) the time lag between policy action and potential policy effectiveness. An overview of the benchmarking approach is presented in figure 2.1.

From a systemic perspective of the innovation process, four broad sub-areas for potential policy intervention in biotechnology innovation systems can be identified (Senker et al. 2001):

(1) the development of the knowledge base and human resources;

(2) knowledge transmission and application;

(3) the market;

(4) industrial development.

These four sub-areas provide the framework for key processes of the innovation system. In order to support these processes, specific policy goals can be formulated for each sub-area.[2] These policy goals firstly can be assigned to seven policy areas, which basically cover the whole range of possible policy portfolios within the policy-making system:

(1) education policies;

(2) research policies;

(3) exploitation policies;

(4) policies related to industrial development;

(5) fiscal policies;

(6) regulation;

(7) demand-oriented policies.

This relationship between policy goals and the seven policy areas allows mapping national policy portfolios with respect to their relevance for biotechnology (*the input*).

Secondly, policy goals can be linked to various output indicators, which allow assessing the extent and way of achievement of policy goals (*the output*). Due to the time lag between policy activity and policy effects, output indicators are only able to

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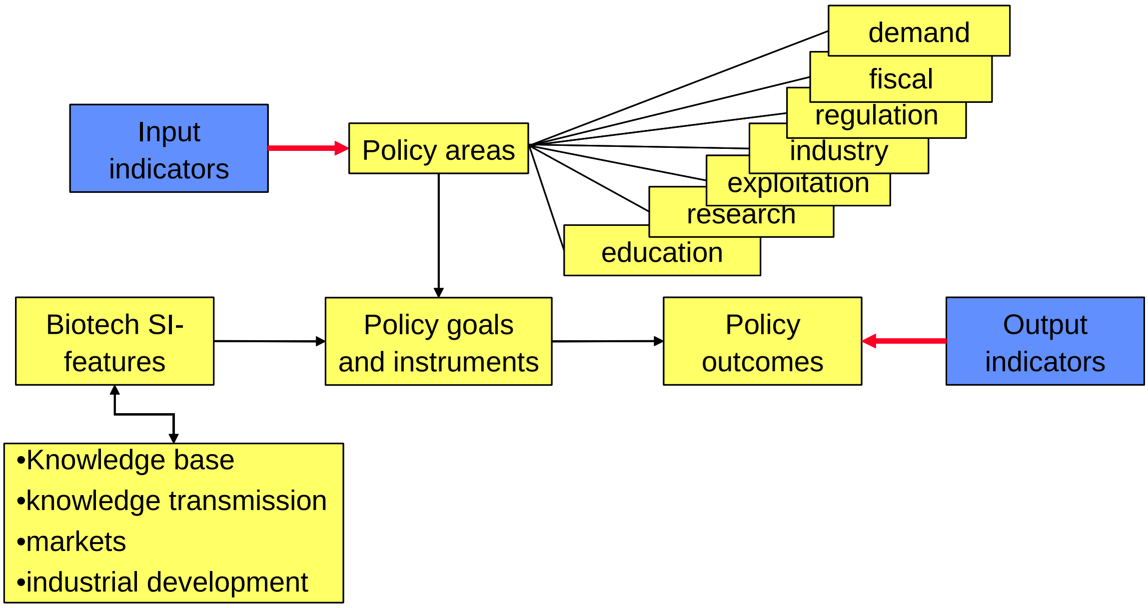
2 The policy goals are summarised in table 2.1 and discussed in detail in annex 2.

assess the achievement of policy goals set in previous years. Based on the analysis of historical data within this project (annex 4) we estimate this time lag to three to five years.

Figure 2.1: Overview of the benchmarking approach (SI: system of innovation)



The described relationships are summarised in table 2.1. The grey fields indicate the assignment of the various policy goals to the given policy areas. In some of these fields a differentiation is necessary between generic policies and biotechnology-specific policies. In such cases light grey represents generic, while dark grey stands for biotechnology-specific policies.

Table 2.1: The benchmarking concept

Sub-areas of the Biotechnology Innovation System	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators
Development of the knowledge base and human resources	1. To promote high level of bio-technology basic research		X[1] X			X			1. Number of biotech publi-cations per capita (pC) 2. Number of citations to biotech publications 3. Number of PhD graduates in life sciences per million capita (pmC)
	2. To promote high level of industry-oriented (and applied) research		X X						
	3. To support knowledge flow between scientific disciplines		X X						
	4. To assure availability of human resources	X							
Knowledge transmission and application	5. To facilitate transmission of knowledge from academia to the industry and its application for in-dustrial purposes			X X		X			4. Number of BT[4] patent applications pC 5. Number of BT companies pmC
	6. The adoption of biotechnology for new industrial applications						X	X	
	7. To assist firm creation	X			X X	X	X		
Market	8. To monitor and improve the social acceptance of biotechnology							X	6. Average responses to Eurobarometer 58.0 (2002) Questions 12, 13, 14 7. Number of drug approvals pmC 8. Number of field trials with GMO crops pmC 9. Volume of production in relevant industry sectors
	9. To facilitate the introduction of new products					X			
	10. To strengthen the economic sectors exploiting biotechnology					X	X		
	11. To keep/attract large firms (im-portant market, important for firm development: tacit knowledge etc.)					X	X		
Industry	12. To encourage business investment in R&D				X		X		10. Number of BT IPO per number of BT companies[2] 11. Number of public BT companies per number of BT companies. 12. DVC[3] invested in biotechnology companies pC 12. DVC invested in high-technology companies pC 13. DVC investments pC
	13. To improve firm's competitiveness	X				X	X		
	14. To exploit regional potentials				X				

1 X represents the "intensity" of respective policies as described in detail in annex 3.2.
2 IPO stands for Initial Public Offerings of biotechnology companies.
3 DVC stands for Domestic Venture Capital.
4 BT: biotechnology

In the following subsections each sub-area of the biotechnology innovation system with its relation to policy goals, policy areas and output indicators is discussed in more detail.

Sub-area "development of the knowledge base and human resources"

The generation and maintenance of a suitable knowledge base (with a balance between basic and applied research) is a key condition for the strength of a biotechnology innovation system. Furthermore, innovation processes in biotechnology draw on the availability of scientists with the necessary competencies to carry out biotechnology-related activities in the industry and in public sector research organisations (PSROs).[3]

Accordingly four main policy goals can be identified:[4]

(1) the promotion of high-level basic research;

(2) the promotion of high-level industry-oriented and applied research in biotechnology;

(3) the support of knowledge flow between scientific disciplines;

(4) securing the availability of qualified human resources.

Indicators for assessing the achievement of these policy goals are mainly based on bibliometric analyses (publication and citation counts). Another indicator should assess the ability of the national education system to provide a sufficient number of scientific personnel for biotechnology:

- number of biotechnology publications per thousand capita (indicator 1 in table 2.1);
- number of citations to the national biotechnology publications (indicator 2, table 2.1) as an impact measure;
- the number of PhD graduates in life sciences per million capita (indicator 3, table 2.1).

Sub-area "knowledge transmission and application"

The transmission of biotechnological knowledge from the sites of its generation to possible loci of application is a key process in the biotechnology innovation system. This process functions mainly via collaboration between industry and academia. We

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3 See annex 1 for definition.

4 Numbers refer to column 2 in table 2.1.

also observe that licensing agreements between public sector research organisations (PSROs) and industry are becoming more important. Finally, firm creation plays an important role in the application of knowledge since start-ups and academic spin-offs are engaged in R&D activities for industrial purposes.

In this sub-area three policy goals can be identified:

(5) to facilitate the transmission of knowledge from academia to the industry and its application for industrial purposes;

(6) to excite the adoption of biotechnology for new industrial applications; and

(7) to assist firm creation.

The necessary data to assess the performance of the innovation system in this sub-area and the achievement of the relevant policy goals are hardly available. For feasibility reasons only two indicators can be considered:

- number of patent applications in biotechnology per capita[5] (indicator 4, table 2.1);
- number of biotechnology companies per million capita (indicator 5, table 2.1).

Sub-area "market"

This sub-area of the innovation system covers the elements of the innovation process that are responsible for the full integration of biotechnology into different economic sectors. This process ends with the successful introduction of biotechnology-based products into the markets. The relevant markets for biotechnology-based products and services at present are the markets for pharmaceuticals, chemicals and agro-food products. In addition, the market for biotechnological processes and methods in the industry needs consideration.

The demand side is comprised by the potential consumers of biotechnology-based products. Furthermore, the strength of relevant economic sectors influences the demand since it determines the extent to which certain industries may adopt biotechnology approaches, thereby increasing demand for such solutions.

In this sub-area we identify four policy goals:

(8) to monitor and to improve the social acceptance of biotechnology;

(9) to facilitate the access of biotechnology-based products to the market;

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5 The patent analysis is restricted to European patents for methodological reasons (see annex 3.3). It should be noted, however, that many European scientists and companies in biotechnology also apply for US patents.

(10) to strengthen the economic sectors exploiting biotechnology; and

(11) to keep and attract industrial leaders in these sectors.

The output indicators aim to assess the social acceptance of biotechnology, the conditions for accessing the markets relevant for biotechnology-based products (pharmaceuticals and agro-food) and the capacity of the national economies to fully benefit from the industrial application of biotechnology. The following indicators are considered:

- responses to the Eurobarometer 58.0 (2002) survey on the public perception of biotechnology in Europe (indicator 6 in table 2.1);
- the number of drug approvals per million capita (indicator 7 in table 2.1);
- the number of field trials with genetically modified (GMO) crops per million capita (indicator 8 in table 2.1);
- the production volume of biotechnology-based sectors (indicator 9 in table 2.1).

Sub-area "industry"

Small and medium-sized enterprises (SMEs) play an important role in the development of biotechnology innovations[6]. They have important system functions such as exploring knowledge, using discoveries for industrial purposes and building interfaces between public research organisations and large firms. The success of biotechnology SMEs depends to a great extent on their innovative performance and their ability to identify and acquire resources to undertake research and development (R&D). For this purpose the effective interaction at the regional level between the companies and the necessary resources (universities and research organisations, venture capitalists, investors, etc.) is essential.

In this context policy goals comprise:

(12) to support business investment in biotechnology R&D;

(13) to improve the competitiveness of biotechnology-based companies; and

(14) to exploit regional potentials and synergies.

The output indicators for industrial development consider mainly two issues: firstly, the financial framework conditions for biotechnology companies and secondly, the quality of the national industrial subsystem of the biotechnology innovation system. The second issue is related to the fact that private financial investments are made only after

6 See annex 1 for definition of biotechnology SMEs.

careful assessments of the performance and perspectives of receiver companies had been made by investing firms. The following indicators are considered:

- the number of initial public offerings by biotechnology companies (IPOs) per number of biotechnology companies (indicator 10 in table 2.1);
- the number of public biotechnology companies related to all biotechnology companies (indicator 11 in table 2.1);
- the total volume of domestic venture capital invested in biotechnology (indicator 12 in table 2.1) or in high-technology sectors if no information on biotechnology is available (indicator 12' in table 2.1) per capita;
- the total volume of domestic venture capital invested in the country per capita (indicator 13 in table 2.1).

3 Implementation of the benchmarking concept

Mapping national biotechnology policy: the national policy profiles

In order to map national policy portfolios with relevance to biotechnology, it is necessary to identify those policy activities that influence the development of biotechnology by targeting the different sub-areas of the innovation system as indicated in table 2.1. Thereby an important part of the input side to the innovation system can be captured. For identifying policy activities in these seven policy areas and important features of the policy-making process a policy questionnaire for policy-makers was developed (see annex 3.1). The questionnaire was designed as a flexible tool which contains a set of core questions covering the basic information required for elaborating and monitoring policy profiles and also specific additional questions that relate to policy issues of specific interest. For example, in the current round of benchmarking the process of implementing EC directives on a country level was explored.

Filling in the questionnaire by policy-makers is the first step in the assessment of the policy input in each country. From the data gathered through the questionnaire a qualitative and a quantitative assessment of the policy input can be carried out (see annex 3.2). The qualitative assessment allows carrying out a general analysis of the policy areas involved in promoting biotechnology. The scheme to carry out the qualitative assessment is presented in annex 3.2. The framework to present the results of the quantitative assessment follows the scheme presented in table 2.1 where the "x" corresponds to the extent of engagement (in a five-point scale) of the national policy in the correspondent area (defined in the top of the table) to reach the related policy goal (defined on the left side of the table). The value measuring the national policy engagement is calculated during the evaluation of the policy questionnaire as described in annex 3.2. In some policy areas we differentiate between generic and biotechnology-specific policy activities. In these cases generic activities are indicated by light grey in table 2.1, all specific activities by dark grey.

Capturing the achievement of policy goals: output indicators

As presented in table 2.1, to capture the achievement of policy goals a set of indicators has been selected. Annex 3.3 discusses indicators' definitions and sources in detail. The selection of indicators draws on two main criteria: availability of data and comparability across countries. It is important to point out that the output indicators capture the performance of the whole sub-area of the innovation system to which they have been assigned to according to table 2.1. Accordingly they aim at assessing the achievement of a *set* of policy goals relevant for each sub-area of the innovation system. Furthermore, the time lag between policy activity and potential outcomes of any policy measures needs to be considered. Since it takes several years until potential policy effects can be detected, the potential outcomes of current policy activities in the various countries cannot be assessed now. Rather, based on the historical analysis we estimate that it will take between three and five years until a comparison between current policy profiles and policy effects will reveal meaningful insights. This implies that it is important to consider the benchmarking exercise as a continuous process which needs to be repeated in the future and which will be enriched by additional analysis of output indicators during future rounds of benchmarking.

Validation of the benchmarking concept using historical data

The approach to benchmarking and the practicability of the benchmarking concept were tested by using historical data. For the old Member States and in addition for the United States and Canada, policy input data for the period 1994/95 were elaborated by the project team according to the structure of the benchmarking concept. These input data were compared to output indicators describing the situation in the various countries in 2002 (or in 2000 depending on data availability). Thereby the time lag between policy activity and potential policy effects was taken into account.

The historical analysis provided a proof of concept of the benchmarking approach. In particular it showed that:

- it is feasible to elaborate the suggested policy input factors on a country level by using the policy questionnaire; and that
- the proposed output indicators provide meaningful information on the achievement of certain policy goals.

The discussion of the detailed policy profiles of each country is presented in annex 4.

Transfer process

In order to make the transfer of the benchmarking concept to interested Member States efficient and successful, the transfer process comprised a number of different steps:

In order to involve interested countries already during the early phases of the project, a draft benchmarking concept was presented at a Commission Biotech Network meeting in Brussels on April 2nd, 2004. Feedback from participating countries was integrated in an updated version of the benchmarking concept. For new Member States in some cases (in addition to policy-makers) national experts were involved, who had the task to collect the information needed for filling in the policy questionnaire and to check the availability of national sources for constructing output indicators.

The benchmarking concept was described in detail in a benchmarking manual which was provided to the Commission Biotech Network. New Member States were informed about the benchmarking concept in a separate meeting on November 25th and 26th in Brussels by the project team. During that meeting not only the benchmarking concept was presented and discussed. In addition, in bilateral discussions all participating new Member States were informed about details of the project. Following this meeting the new Member States were contacted by the project team and asked for participation in the benchmarking project. Policy questionnaires were disseminated to all participating countries. Additional information was provided by the project team via phone discussion, personal discussions and e-mail communication. Where necessary, missions to new Member States were made to discuss the implementation of the concept in detail.

In the following table those countries are listed which participated in this first round of the benchmarking.

Table 3.1: Overview of Member States participating in the benchmarking project

Old Member States	**New Member States**
Austria	Czech Republic
Belgium	Estonia
Denmark	Hungary
Finland	Lithuania
France	Poland
Germany	Slovakia
Ireland	Slovenia
Italy	
Luxembourg	
Netherlands	
Portugal	
Spain	
Sweden	
United Kingdom	

Taken together 21 Member States participated in the first round of benchmarking. From the old Member States only Greece was not interested in participation. Concerning the new Member States, Cyprus, Latvia and Malta did not participate for various reasons. In the case of Cyprus no information about policy contact persons was available, so that the country could not be included. The representative of Malta expressed some interest in the project during the meeting in November 2004, however, no positive reaction concerning participation was obtained by the project team before the termination of the project. Latvia was very interested in participation and might join the exercise in the next round. Presently, due to lack of time and resources participation was not possible.

4 Benchmarking results across European Member States

In this section the empirical results of the first round of benchmarking are presented. The first part (chapter 4.1) presents general policy trends over the last decade. In the second part (chapter 4.2) specific policy approaches towards biotechnology in the seven policy areas are discussed with respect to their effectiveness[7].

4.1 Policy trends

Table 4.1 presents an overview of the European biotechnology policy landscape in 1994/95. For comparison, policy profiles of the USA and Canada are included. Data for 1994/95 has been collected by the project team based on various policy documents and in particular on the previous EPOHITE and INVENTORY projects, where a thorough analysis of European biotechnology policies had been performed (Reiss et al. 2003, Enzing et al. 1999). National policy-makers provided the information for biotechnology policies of 2004 summarized in tables 4.2 (old Member States) and 4.3 (new Member States) and checked the detailed analysis on a *country level* presented in annex 4. Table 4.4 summarises the output indicators collected for the old Member States, USA and Canada by the project team.

7 It should be noted that this project did not aim at providing a detailed assessment of specific biotechnology policies. Rather, the main goal was to develop a tool for benchmarking biotechnology policies. The recently started Specific Support Action "BIOPOLIS" within FP6 will fill this gap by making detailed comparative analyses of specific biotechnology policies in all Member States including an evaluation of budgets of public biotechnology programmes.

Table 4.1: Overview of biotechnology policies in the old EU Member States, USA and Canada in 1994/95 (*expert's assessment)*

Policies	AT	BE	DE	DK	ES	FI	FR	GR	IL	LU	IT	NL	PT	SE	UK	US	CA
1. Education																	
1.1 biotech curricula		√	√	√	√	√	√		√	n. d.	√	√	√	√	√	√	
1.2 business issues		n. d.		√						n. d.			n. d.	n. d.			
2. Research																	
2.1 biotech promotion	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
3. Exploitation																	
3.1 entrepreneurship/spin-offs		√	√	√		√	√	√	√	√	√	√		√	√	√	√
3.2 industry/PSRO collaboration	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√
4. Industrial development																	
4.1 availability of capital	√	√	√	√		√	√		√		√	√	√	√	√	√	√
4.2 business supp. f. start-ups		√	√	√	√	√	√		√		√	√	√	√	√	√	√
4.3 industrial research (bt specific)	√		√		√	√			√			√	√	√		√	√
4.4 clusters		√	√	√	√	√	√			n. d.			√	n. d.	√	√	√
5. Fiscal																	
5.1 tax incentives for innovation		√			√		√		√	n. d.	√	√	√		√	√	√
6. Regulation																	
6.1 task innovation					√	n. d.	√		n. d.	n. d.	√		√	√	n. d.	√	√
7. Demand																	
7.1 explore bt benefits	√	n. d.	√	√		√	√			√		√	n. d.	√	√	√	√
7.3 adoption		√	√							n. d.			n. d.	n. d.	√	n.d.	

√ = policies in place, n. d. = no data, blank = no such policies in place.

AT: Austria, BE: Belgium, DE: Germany, DK: Denmark, ES: Spain, FI, Finland, FR: France, GR: Greece, IL: Ireland, LU: Luxemburg, NL: Netherlands, PT: Portugal, SE: Sweden, UK: United Kingdom, US: USA, CA: Canada

Table 4.2: Overview of biotechnology policies in old EU Member States in 2004 (national policy-maker's assessment)

Policies	AT	BE	DE	DK	ES	FI	FR	IL	LU	IT	NL	PT	SE	UK
1. Education														
1.1 biotech curricula	√	√	√	√	√	√	√	√		√	√	√	√	√
1.2 business issues	√				√	√	√	√		√	√	√	√	√
2. Research														
2.1 biotech promotion	√	√	√	√	√	√	√	√	√	√	√	√	√	√
3. Exploitation														
3.1 entrepreneurship/spin-offs	√	√	√	√	√	√	√	√	√	√	√	√	√	√
3.2 industry/PSRO collaboration	√	√	√	√	√	√	√	√	√	√	√	√	√	√
4. Industrial development														
4.1 availability of capital	√		√	√	√	√	√	√	√	√	√	√	√	√
4.2 business supp. f. start-ups	√	√	√	√	√	√	√	√	√	√	√	√	√	√
4.3 industrial research (bt specific)		√	√	√	√	√	√	√	√	√			√	√
4.4 clusters	√	√	√	√	√		√	√		√	√			√
5. Fiscal														
5.1 tax incentives for innovation	√	√		√	√		√	√		√	√	√	√	√
6. Regulation														
6.1 task innovation	√		√	√	√	√	√	√	√	√	√	√	√	√
7. Demand														
7.1 explore bt benefits	√	√	√	√	√	√	√	√	√	√	√	√	√	√
7.3 adoption				√	√	√	√	√					n. d.	√
8. Policy processes														
8.A Impact assessment			√			√	√	√		√	√		√	√
8.B Policy coordination	√	√		√	√	√	√	√		√				√

√ = policies in place, n. d. = no data, blank = no such policies in place.

Table 4.3: Overview of biotechnology policies in the new EU Member States in 2004 *(national policy-maker's assessment)*

Policies	CZ	EE	HU	LT	PL	SK	SI
1. Education							
1.1 biotech curricula	√	√	√	√	√	√	√
1.2 business issues					√		√
2. Research							
2.1 biotech promotion	√	√	√	√	√	√	√
3. Exploitation							
3.1 entrepreneurship/spin-offs		√	√	√			√
3.2 industry/PSRO collaboration		√	√	√	√		√
4. Industrial development							
4.1 availability of capital		√	√	√			√
4.2 business supp. f. start-ups		√	√	√			√
4.3 industrial research (bt specific)			√				
4.4 clusters							√
5. Fiscal							
5.1 tax incentives for innovation			√			√	
6. Regulation							
6.1 task innovation			√		√	√	√
7. Demand							
7.1 explore benefits	√	√			√	√	
7.3 adoption		√		n. d.			
8. Policy processes							
8.A Impact assessment		√					
8.B Policy coordination							

√ = policies in place, n. d. = no data, blank = no such policies in place.

A comparison of the national portfolios between the countries and between the different periods considered reveals the following observations.

Reinforcement of public policies in favour of biotechnology

The main policy evolutions between 1994/95 and 2004 can be portrayed as follows:

- Biotechnology remains a priority for policy-makers. A wide range of public policies has been designed and implemented in most countries. Comparing the current (2004) policy portfolios with the situation of 1994/95 reveals that the national policy approaches became more comprehensive and intensive. This seems to indicate that higher priority has been given to biotechnology in recent years.
- Biotechnology remains a science-based sector. Policies supporting research and education have been in place in most countries in both periods considered.
- Supporting specific biotechnology education measures has been on the agenda of most countries in the mid1990s and maintained its importance in the current profiles of old and new Member States.
- Considering business issues in biotechnology education was not widespread in 1994/95 in Europe and also in the USA and Canada. In recent years most of the old Member States took action in this field by implementing initiatives to support business studies courses in university science degrees in biotechnology. Obviously, the problem of lacking business know-how in science curricula has exerted some impact on the policy agenda in several countries. Among new Member States so far only few countries have followed this trend. This difference might be explained by the different state of biotechnology in both groups of countries. Most old Member States have well developed biotechnology sectors where a lack of business know-how among scientists has been discussed for some time. In the emerging sectors of most new Member States such problems might not have arisen so far. However, taking into account the experience of old Member States we recommend to consider this education issue rather early because it takes time to build up such knowledge.
- Most countries also support the exploitation of public biotechnology research via the stimulation of entrepreneurship, spin-offs and collaborative biotechnology research between industry and public sector research organizations.
- Policy instruments to support industrial development in biotechnology are related to improving the availability of financial capital and various forms of business support for start-ups. One of the main mechanisms for industrial development remains start-up creation. Public policies towards industrial development remain stable even if the biotechnology sector is maturing. Firms are growing, barriers to entry are becoming higher and entry may be more and more difficult. Direct support for industrial research and initiatives to support existing firms and large firms are not completely generalised even in 2004.

- Policies aiming at creating biotechnology clusters[8] have been less favoured policy instruments in 1994/95 implemented only in about half of the European countries while such approaches were already widespread in the USA and Canada. In recent years old Member States are paying more attention to cluster policies. On the other hand in new Member States, policies aiming at supporting clustering are lacking (almost) completely. As we focus on national policy instruments, we may not be able to identify regional policies. However, as the sector matures and biotechnologies are closer to the market, clustering effects may be different. Indeed, most of the clusters have been designed around scientific poles. During the emerging phase, the markets for biotechnology products and services were around large universities and research centres. As the industry matures, other – more downstream – markets are targeted and it could be reasonable to locate firms around large firms in life sciences rather than close to universities.

Creating a favourable environment for biotechnology

In addition to direct intervention like subsidies for start-ups, subsidies for university/ industry research or for basic research, policy-makers increasingly tend to create a favourable environment for investing in risky projects like, for example, in biotechnology.

- Fiscal policy instruments to promote innovation activities related to biotechnology have become widespread in the old Member States between 1994 and 2004. However, only few new Member States have implemented such measures.
- Policy-makers pay more attention to regulatory issues. Almost all old Member States and already about half of the new Member States are taking into account the impact on innovation when designing new regulations for biotechnology. As the sector matures, regulation seems to become more stable (patents, GMOs, dissemination, etc.). The stability of the regulatory environment is one of the conditions to reduce uncertainty and to create a favourable environment for innovation.

Promoting demand

- Policy-makers increasingly consider the demand side of biotechnology. This is one of the main areas of new public policies. A number of countries have policies in place to support initiatives for exploring the benefits, costs and risks of the application of biotechnology. They also develop consultation procedures to improve the dialogue with the consumers. Countries are also concerned with policies

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8 It should be noted that the term cluster is used differently in various countries. For example, in the case of Finland cluster means industrial cluster and not regional cluster or scientific poles. In the context of this project the term clusters refers to the interaction between companies and research organisations at a regional level (see annex 2, policy goal 14).

stimulating the adoption of biotechnology for new industrial applications by companies that are not performing biotech R&D themselves.

- This trend towards paying more attention to the demand side is restricted mainly to the old Member States. In new Member States we observe only minor policy activities devoted to this area. The rather early stage of biotechnology in most of the new Member States might explain this lack of demand-oriented approaches. However, it also might be interesting for new Member States to observe how countries with a more mature biotechnology sector are tackling the demand side, and learn which policy approaches seem to work in this respect.

Adapting public policies to national characteristics

The overview of policy trends in biotechnology across European countries indicates some degree of convergence between countries. Policy portfolios seem to become more similar. However having a closer look at specific developments at a national level (see annex 4) reveals that the national policy approaches increasingly aim at reinforcing strengths and reducing weaknesses of the national biotechnology innovation systems. This indicates that policies are adapted to different national situations. This will contribute to maintaining national diversity in the European research era.

Biotechnology policy portfolios of new Member States

Compared to the old Member States, the policy portfolios of new Member States are less comprehensive and patchier. Most countries focus on education, research and exploitation policies. Industrial development seems to have a lower priority. As discussed above, creating favourable framework conditions for biotechnology is considered only by few new Member States.

Policy-making process

Two issues of the policy-making process were considered in the analysis of current policy approaches in the Member States: impact assessment of policies and policy coordination. The analysis of policy processes in new Member States reveals that policy coordination is no issue in these countries and only one of the countries has installed some mechanisms for a policy impact assessment. In the case of the old Member States, policy impact assessment also seems to be less widespread. Only eight countries report on such measures.

More emphasis is given to policy coordination. Nine countries indicate to have implemented formal mechanisms for that purpose. Taking into account results of previous research (Reiss et al. 2003) where a positive impact of *ex ante* policy coordination on national performance in biotechnology has been observed this trend toward increasing consideration of coordination between different policies and between the responsible agencies is expected to contribute to increasing policy effectiveness. However since it will take some years until such outcomes can be detected using performance indicators, future rounds of benchmarking will be needed to identify the expected positive effects.

4.2 Policy effectiveness

In this section a comparison is made between performance of countries (see table 4.4) and the respective policy settings based on the country analyses presented in annex 4. In this context it is important to note the time lag between policy activity and potential outcomes of any policy measures. Since it takes at least several years until potential policy effects could be detected, the potential outcomes of the current policy profiles in the various countries can not be assessed now. Therefore the following discussion considers the relation between policies in place at the mid 1990s and current biotechnology performance.

This comparison allows discussing the effectiveness of various policy approaches. However it should be noted that simple correlations between policy input and national performance are not adequate because policy is only *one* among several factors (such as specialisation and performance of the industry, traditions, institutional settings) having an impact on performance.

The following areas will be considered in this section:

- policies supporting the creation and maintenance of the knowledge base,
- policies supporting the exploitation of biotechnology research,
- policies aiming at improving social acceptance of biotechnology,
- policies supporting market access for biotechnology products,
- policies aiming at improving industrial development of biotechnology.

Knowledge base policies

In terms of performance as measured by publication and citation indicators (table 4.4) we observe that Sweden, Denmark, the United Kingdom, the Netherlands and Finland as well as the USA and Canada are clearly above the European average. Belgium, Germany and France are performing a little better compared to the average value.

Table 4.4: Normalised output indicators[9] for the old EU Member States, US and Canada. Historical Analysis 1995–2002

	BT Publications 1995-2000	Citations to BT publications 1995-2000	Number of PhD graduates in life sciences 2001*	BT Patent applications 1995-2002	Buitechnology companies 2002*	Acceptance Index Eurobarometer 2002**	Bio-medicines (Approvals) 1995-2002	Number of trial-traits 1996-2001	Production*** 1995-1999	IPOs 1995-2002	Public Companies 2002*	Bio Venture Capital 1995-2002	Total Venture Capital 1995-2002
AUSTRIA	88	116	53	102	109	100,89	0	11	76	0	0	12	27
BELGIUM	118	117	128	166	99	100,59	0	193	128	46	44	206	69
DENMARK	190	110	85	317	207	101,18	1190	134	13	211	202	279	56
FINLAND	142	120	62	112	217	100,18	0	122	141	42	40	104	103
FRANCE	103	111	29	83	60	101,12	98	193	120	93	76	93	142
GERMANY**	89	126	52	124	65	**	49	36	84	158	109	190	61
GREECE	26	63	n.a.	7	n.a.	101,05	0	61	120	0	0	0	3
IRELAND	80	83	301	74	133	100,28	0	30	n.a.	91	173	30	66
ITALY	52	90	77	25	13	100,58	0	122	101	249	178	8	89
LUXEMBOURG	28	54	n.a.	29	n.a.	101,58	0	n.a.	n.a.	0	0	n.a.	n.a.
NETHERLANDS	148	127	34	154	78	101,29	0	77	117	149	107	155	183
PORTUGAL	30	58	n.a.	3	30	99,35	0	25	87	0	0	4	24
SPAIN	60	72	92	14	9	98,67	0	135	166	0	0	9	60
SWEDEN	204	119	81	176	298	100,34	65	191	31	89	152	192	222
UK	143	134	306	113	83	98,11	98	69	116	373	420	119	294
US	121	171	171	170	75		231	698	65	411	656	575	321
CANADA	132	129	196	91	197		37	834	94	198	616	928	267
EU Average	100	100	100	100	100	100,29	100	100	100	100	100	100	100

*** or latest availiable year**
**** For Germany the Acceptance index can only be calculated for the Old Fedearl States (OFD) and the New Federal Sates (NFS) separetly: 101.70 (West) and 100.41 (East)**
***** Production includes only the per capita volume of those industrial sectors that are relevant for the application of biotechnology**

9 The indicators have been normalised with respect to the EU average (EU average = 100). The raw data has been included in annex 5. All indicators are based on relative figures which take into account different sizes of the various countries (see annex 3.3 for details). Figures for drug approvals in Denmark (bio medicines) reveal a strong specialisation of that country. However, there is also a statistical artefact due to several approvals in 2002.

Looking at policies in place supporting the knowledge base firstly reveals the effect of financial commitment to supporting biotechnology. Support for research related to biotechnology has a high priority in most well performing countries as indicated by high shares (> 5 %) of biotechnology R&D in GDER. A second issue concerns the relation between biotechnology-specific and generic policies. Having specific policies for biotechnology pays off in a stage where biotechnology is at the verge of a pronounced take off, as was the case in Europe during the mid 1990s. Sweden, Denmark, The United Kingdom and Belgium present examples for such approaches. Having only (or mainly) generic instruments during such a stage as was the case for example in France, Austria, Ireland or Spain is less effective. The balance between support for basic and applied research is another policy variable having impact on performance. Most well performing countries (e. g. the Netherlands, Belgium, Germany, the USA and Canada) gave equal emphasis to both areas or had some stronger focus on supporting basic research (e. g. Sweden, Denmark and the United Kingdom).

Support for international mobility of researchers was not highly ranked on the political agenda. However, where it has been implemented (e. g. Sweden, Denmark or Finland) it seems to be beneficial to the output. This observation is in particular important for smaller countries which might depend to a greater extend on a external input due to (natural) limitations in the diversity of their domestic knowledge base.

Considering the supportive function of regulation is an additional complementary asset when building up a good knowledge base (e. g. Sweden and the Netherlands). However such an approach alone without suitable instruments to support research directly is not sufficient as indicated by the experience in Italy and France.

Policies to support exploitation of biotechnology research

As measured by the intensity of firm creation and patenting activities Denmark, Sweden, Finland, Belgium, the Netherlands as well as the USA and Canada are performing above the European average. Ireland has a good performance in firm creation, the United Kingdom and Germany in patenting.

The analysis of policies to support knowledge transmission firstly indicates that having only generic exploitation policies is not sufficient (e. g. France, Italy). Well performing countries (e. g. Denmark, Sweden, Finland, Belgium, and the Netherlands) have implemented a mix of generic and biotechnology-specific measures. The USA and Canada seem not to comply with this observation; they have followed mainly generic approaches. This difference might be related to the advanced stage of development of the sector in these countries, where generic approaches might be more appropriate.

A second observation relates to the combination of different policy instruments aiming at supporting exploitation. It seems to pay off to combine infrastructural instruments with support measures. For example in the case of building up technology transfer structures providing support for patenting via financial incentives (e. g. Finland) or education measures (e. g. Denmark) seems to be superior to approaches providing just infrastructures. A similar observation is made for policies supporting industrial development. Support for infrastructure alone (e. g. facilities in bio parks) is not very effective. Adding service functions such as advice on IPR, management, financing and regulatory issues contributes to enhancing the effects of infrastructural measures considerably. Positive examples for such approaches include Ireland, Sweden, Finland and Denmark but also the USA and Canada.

The case study on technology transfer instruments (annex 6.1) provides additional hints on the effectiveness of exploitation policies. In particular it could be shown that the main success factors for technology transfer comprise the following elements:

- closeness of technology transfer experts and institutions to research;
- building up technology transfer teams that combine specific expertise in biotechnology with business and commercialising research;
- giving explicit technology transfer responsibilities to all involved actors (researchers and technology transfer supporting institutions; this includes the stimulation of researchers to consider technology transfer issues;
- considering of the entire value chain in technology transfer;
- building a long-term and realistic vision on start-ups.

Comparing European countries with the USA and Canada reveals some interesting differences in their approaches towards exploitation. In particular the latter two countries seem to have paid more attention to creating supportive framework conditions for exploitation. Regulations related to IPR at universities, IPR in general, company creation, access to private capital and hiring foreign staff have been important fields of policy action in the USA and Canada. In addition fiscal instruments supporting SME and spin-offs (and large firms in the USA) have been common there.

Policies to improve social acceptance of biotechnology

The performance indicators for social acceptance (table 4.4) present best values for Luxembourg, the Netherlands, Denmark and France. The analysis of policy approaches in these countries compared to other countries with less positive outcomes (e. g. Ireland, Finland, Portugal or the United Kingdom) allows the following conclusions. It seems to pay to develop a comprehensive policy approach in this field which includes a broad variety of different measures (technology assessment, foresight, workshops, and infrastructures) as was the case in Denmark and the Netherlands. In this context it is important to include all potentially affected stakeholders and to have a rather broad view of issues to be considered.

Policies to improve market access for biotechnology

Many biotechnology firms do not develop any products for end consumers. Rather they provide technologies and intermediate products for other, mainly large, firms. Therefore the presence of strong industrial sectors where biotechnology could be utilized is an important market dimension for biotechnology firms. The output analysis based on production volume per capita figures indicates that Finland, Belgium, the Netherlands, Spain, France and the United Kingdom have well developed industry sectors with relevance for biotechnology. Italy and Canada are performing at average; all other countries are below the European average.

Except the United Kingdom and Finland all high performance countries had fiscal instruments in place during the mid 1990s which aimed at supporting innovative activities of large firms. Countries not performing that well in this respect did not have such instruments. Canada and the USA also used such instruments, however at least in the USA no positive correlation to output could be observed.

This mismatch could be explained firstly by a size effect. Due to the large size of the American industry, potential technology markets for biotechnology firms are large enough in absolute terms even if the relative size as measured in our output indicator is small. Other explanations take into account the well known lead of the American biotechnology industry compared to Europe. Accordingly American biotechnology firms have a more international orientation their European counterparts so that their technology markets are not restricted to the USA. The high number of cooperations of European pharmaceutical firms with American biotechnology firms supports this notion (Reiss and Hinze 2004). Furthermore, American biotechnology firms are using direct market access strategies more intensively. They offer a number of products (e. g. biopharmaceuticals) and not just technologies reflecting the more advanced state of the American industry. The biomedicines indicator of the USA (table 4.4) which is highest among all countries supports this notion.

In summary this analysis shows that fiscal measures to facilitate innovative activities of large firms seem to work and contribute to generate a large domestic "technology market". Such instruments are in particular important in early stages where no direct product marketing is possible.

Policies to improve industrial development

With respect to indicators measuring the success of the biotechnology industry at stock markets (IPO, market cap) the United Kingdom, Canada and USA are performing exceptionally (table 4.4). Italy and Denmark also present good performance. The lack of data availability for European countries, especially for market capitalisation, makes it difficult to identify any relationship between policy and performance in this area. However, the experience of the USA and Canada points to the importance of regulations and fiscal measures in facilitating going public.

The venture capital indicators reveal a very good performance by Sweden, the United Kingdom, the Netherlands and Denmark. However the USA and Canada are performing even better. Belgium, Germany, France and Finland are also above average; all other countries are performing rather weakly. The policy analysis reveals only few hints on successful strategies. The American example points to the significance of fiscal approaches which seem to pay in the USA.

5 Assessment of the benchmarking process and recommendations for improvement

5.1 Assessment by participating countries

The goal of the benchmarking project was not only to develop and implement a concept for a policy benchmarking, but also to provide an assessment of the benchmarking exercise including recommendations for future rounds of benchmarking. Therefore, all respondents in the participating countries were asked to express their views on the manageability, the coverage and the usefulness of the benchmarking concept.

Usefulness

Altogether, the participating policy-makers have been very positive about the benchmarking. Concerning the policy questionnaire there was broad agreement, that its role as an information retriever and an awareness enhancer is being fulfilled. An additional reason for enthusiasm from new Member States about the initiative relates to the fact, that biotechnology policies are gaining importance in these countries and are currently being designed. Therefore, the concept of the policy questionnaire was perceived as a very helpful feedback on the domestic policy design process. For example it was expressed, that it contributes to identifying key policy issues that had not been considered before. In the context of these policy-making processes, also the terminology of the questionnaire was considered as extremely useful. Most respondents also agreed on the notion that the usefulness of the benchmarking will increase substantially if the exercise is repeated periodically. Some even argued that repetition is a pre-condition for usefulness.

The benchmarking process

The manageability of the policy questionnaire was considered as well. In particular, terminology was perceived as clear and transparent. Accordingly, filling in the questionnaire was possible for most countries in a rather short period of time (below one hour). As far as the coverage of the questionnaire is concerned, all issues were considered as highly relevant.

A key issue of the benchmarking process is the organisation of collecting information. The experience with the first round of benchmarking showed, that gathering the policy input information using the questionnaire can work well locally. Even so, in particular representatives of new Member States argued that the success of the benchmarking exercise could be improved if a certain subset of information on policy activities would be gathered centrally, in order to improve the comparability of policy profiles across countries. Concerning the proposed output indicators, there was broad agreement among the participating countries, that for comparability reasons and also for reasons of required expertise and resources it would be most helpful to install a central data-gathering procedure.

With respect to indicators, some suggestions for additional input and output indicators were made. On the input side, information on public and private R&D budgets in a time series was called for. Unfortunately, presently such information is not available in a comparable way since there are no official biotechnology statistics. Other important indicators would cover public-private partnerships and collaboration, which can be both an input and an output of the biotechnology innovation systems. During the development of the benchmarking concept, the project team among others had tested the feasibility of such indicators and came to the conclusion that presently there are no reliable sources available for constructing such indicators. Concerning citations and patents, some suggestions were made to link such information to mobility of PhD students. In addition it was argued, that the technology balance of a country (import–export of biotech products) could be an indicator of competitiveness of the sector in each country. Both suggestions are very interesting; however, our searches for suitable sources of indicators during this project gave reasons for some doubt of the availability and feasibility of such complex indicators.

Recommendations

Some specific recommendations on definitions and wordings in the questionnaire were made by the participating experts. These recommendations were taken up and used for the elaboration of an improved version of the questionnaire (annex 3.1). In addition, there were some discussions of additional issues which might be considered in future rounds of the benchmarking. For example, the interrelation between European policies and national policies was suggested as an interesting additional issue which might be taken up as a new module in future benchmarking rounds. Such questions would help to investigate whether national and European biotechnology policies are substitutes or complementary. A generalisation from these recommendations concerns the internationalisation beyond European borders. In general, it was recommended to use the questionnaire in future benchmarking rounds also as a tool to adopt additional interesting issues depending on the future evolution of biotechnology in Europe.

The most important recommendation made by the participating countries is, that the benchmarking – and in particular the policy survey – must be repeated in the future in order to become fully exploitable and useful. Thus, for example if responses would be biased, one could compare responses over time rather than across Member States. This implies that although the questionnaire should evolve and reflect changes in biotechnology policies, a substantial share of the questions should remain in the current form as a core set for gathering policy information.

In this context the frequency of repetitions is an important issue. Considering the time lag between policy activity and potential policy outcomes it seems feasible to assess current policies in about three to five years by using the elaborated output indicators. Therefore, a repetition of the benchmarking every five years would seem reasonable. On the other hand, it is important to maintain some sort of continuity in different rounds of benchmarking. If the time gap between two rounds would be too long, policy-makers might have difficulties to trace the development of their policy portfolios over time, not least due to responsible persons changing positions in the policy-making system. Against this background shorter periods of about two years might be more advantageous.

Concerning the output indicators, the main recommendation is that a central procedure for gathering such indicators would be highly appreciated and would not only improve but even be a pre-requisite for having available comparable output data.

5.2 Limitations of the benchmark approach: the role of case studies

The policy benchmarking project aims, among others, at improving the understanding of the impact of public policies on biotechnology innovation processes and at developing methods for measuring this impact. The approach used in this project – providing short overviews of a country’s policies and its performance – is mainly quantitative by character. It provides policymakers in the Member States with high density information bits (the profiles), on the basis of which they can benchmark their profiles with those of other countries. This approach has some limitations. Firstly, for specific policy areas no suitable performance indicators can be defined a priori. A second limitation is that the profiles are just a starting point, not providing detailed information on specific policy instruments. On the basis of these profiles, policymakers will discuss what is behind the data. They need more information about the policy instruments themselves: their goals, lay-out, budgets, conditions, stakeholders involved, target groups etc. in order to discuss best practice and what they can learn from them for their national policy goals. For these reasons and also in order to elucidate the relationship between policies and impact in more detail, the project also includes two case studies.

Most public programmes for the development of biotechnology focus on promoting research and on supporting biotechnology start-ups. Given the importance of technology transfer and valorisation instruments in tackling the European paradox, the two case studies address policy instruments in this category. The first case study on the Flemish policy instrument VIB provides an in-depth analysis of best practice technology transfer in biotechnology in Belgium. The second case study gives an overview of policy approaches in Europe to support biotechnology adoption by established companies and discusses in more detail the Bio-Wise programme of the United Kingdom. See annex 6 and 7 for the case study reports.

VIB's technology transfer activities

Technology transfer instruments are widely used to turn science into innovative and commercially viable applications. However, an analysis of the effectiveness of technology transfer instruments in 14 EU Member States showed that scientists and representatives from firms gave rather negative assessments of the technology transfer organizations in their countries. Nevertheless, the analysis also reported some positive exceptions including the Flanders Interuniversity Institute for Biotechnology (VIB) in Belgium (Reiss et al. 2003). The VIB case study examines in more detail the organization and performance of VIB in technology transfer as well as the factors that play a critical role in the successful performance of VIB.

VIB was established in 1995 as a virtual research institute, in which a number of Flemish universities participate. In addition, VIB was given the tasks of stimulating and facilitating technology transfer of VIB's research. The technology transfer activities of VIB can be considered as very successful. Despite its rather limited budget (6 % of the annual operating income), it has identified more than 350 inventions, it has a portfolio of 143 active patent families, it has established almost 200 collaborative agreements with industrial partners and it prepared four start-ups. Flemish researchers and companies praise VIB's pro-active attitude, the high qualified officers that advice and support the researchers, as well as the availability of seed-money for spin-offs.

When analyzing the technology transfer organization and activities in more detail, several factors seem to be critical. One of the most important factors is the very short distance between the technology transfer unit and the VIB research departments. In this way, the unit has a sound picture of the research activities and opportunities for commercialization. A second factor is the expertise of the technology transfer team. All have scientific background in biotechnology, but are also highly experienced in business and commercializing research. In addition, VIB has defined explicit responsibilities for technology transfer at each level in the VIB organization, not just the technology transfer unit, but also the research directors and researchers themselves. Furthermore, VIB's activities address all relevant stages of the technology transfer value chain: from identification of inventions to the appropriation of intellectual property rights and finally the commercialization through licensing agreements, collaborations and spin-offs. VIB's researchers are considered as an indispensable link in the technology transfer process. They are stimulated to think in terms of commercializing their research. They know their research project best and have an excellent view on the innovative values of the outcomes. Finally, VIB has a long-term and realistic vision on the establishment of start-ups. It seems not to be interested in large numbers of start-ups, but prefers to concentrate its efforts and resources on creating a selective number of sustainable start-ups.

Policy approaches in Europe to support biotechnology adoption by established companies

An effective approach to promote the development and diffusion of biotechnology is the support of biotechnology adoption by established companies. The regulatory framework can support the diffusion of biotechnology by both penalizing alternative technologies and by creating incentives for the application of biotechnology.

The lack of awareness of the possibilities of biotechnology, the lack of competencies or capabilities in biotechnology and the difficulties in quantifying the adoption costs prevent companies from undertaking technological changes in their production processes. Accordingly, the case study identifies the increase of companies' awareness of the possibilities of biotechnology and company access to capabilities in biotechnology as key policy goals. Regarding the access to capabilities in biotechnology the case study points out the need of promotion schemes to distinguish between the support of adoption processes involving the application of standardized biotechnological solutions and adoption processes involving the development and implementation of novel biotechnological applications

Bio-Wise basically seems to have reached the policy goals of creating awareness of the opportunities of biotechnology and supporting established companies in the biotechnology adoption process, even though the extent of these effects was lower than expected. In the case study analysis four main elements are identified that influence the results of the Bio-Wise programme: the strong internet presence to raise awareness of biotechnology opportunities, the broad set of supporting initiatives included in the programme, the incentives for programme participants to disseminate their knowledge and experiences and finally the focus on supporting networking activities between industry actors.

5.3 Conclusions

The assessment of the benchmarking by participating countries combined with the experience made by the project team during carrying out this projects allow the following conclusions and recommendations:

(1) The benchmarking concept developed by the project team in close interaction with the Commission Biotech Network provides suitable tools for assessing national policy portfolios.

(2) In particular the policy questionnaire enables collecting systematically data on the whole set of national policies with relevance for biotechnology. The questionnaire exerts indirect positive effects in enhancing awareness of the diversity of policy approaches aiming at supporting biotechnology.

(3) The proposed output indicators provide suitable measures for assessing possible effects of policy actions taken in previous years. The time lag between policy activity and policy outcomes is estimated to three to five years.

(4) The benchmarking also revealed a number of limitations of output indicators:

- The quality of some basic indicators such as the number of biotechnology firms per country is weak since there are no comparable official biotechnology statistics available.
- The coverage of some output indicators that are based on OECD data (PhD graduates in life sciences, production volumes in industry sectors relevant for biotechnology) or on the Eurobarometer surveys is limited. Not all Member States are included in such data.
- Important additional indicators on public or private R&D budgets in biotechnology, on PhD graduates in biotechnology, on industrial research staff in biotechnology, on collaboration between public sector research organisations and biotechnology firms are not available at present.
- For comparability reasons it is not feasible to gather the output indicators only locally.

(5) In order to take full advantage of the benchmarking process, it is necessary to detect dynamic changes in the evolution of policy activities on a national and on a European level. For that purpose it is important to repeat the benchmarking periodically. Repetition is also crucial for detecting possible outcomes of current policy activities due to the time lag between policy activity and policy outcome. Longer intervals might be better suited for detecting policy outcomes, however, there is a danger of losing continuity which is needed to monitor the evolution of biotechnology policies if the interval between two benchmarking exercises becomes to long. As a compromise we recommend to consider intervals of two to three years between two benchmarking rounds.

(6) In future rounds of benchmarking the policy questionnaire can be used as a basic tool to retrieve policy information. In order to monitor dynamic changes, a core

set of policy questions (questions 1 to 7 of the current version of the questionnaire) should stay the same. In addition, policy issues of specific interests can be added to the questionnaire. Based on the discussions with the members of the Commission Biotech Network we recommend in particular to consider questions focusing on the relation between European and national policies with relevance for biotechnology in the next round of the benchmarking.

(7) For the implementation of the next round of benchmarking a differentiation between information on policy input and output indicators needs to be made:

- Policy input information can be gathered locally by interested policy-makers using the benchmarking manual and the policy questionnaire.
- As long as harmonised basic statistical data on biotechnology is not available it is strongly recommended to collect output indicators centrally following the instructions summarised in the benchmarking manual.

6 Literature

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Annex 1: Definitions

1. Definition of biotechnology

The benchmarking project applies a definition of biotechnology which has been developed by the OECD for statistical analyses of biotechnology (Devlin 2003[10]). This definition consists of two parts:

(1) a single definition providing a general description of what biotechnology is about:

'*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*'.

(2) a (indicative, not exhaustive) list of biotechnologies as an interpretative guideline to the single definition:

1. **DNA (the coding)**: genetics, pharmaco-genetics, gene probes, DNA sequencing/synthesis/simplification, genetic engineering.
2. **Proteins and molecules (the functional blocks)**: protein/peptide, sequencing/synthesis, lipid/protein engineering, proteomics, hormones, and growth factors, cell receptors/signalling/pheromones.
3. **Cell and tissue culture and engineering**: cell/tissue culture, tissue engineering, hybridisation, cellular fusion, vaccine/immune stimulants, and embryo manipulation.
4. **Process biotechnologies**: bioreactors, fermentation, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation and biofiltration.
5. **Sub-cellular organisms**: gene therapy, viral vectors

10 Devlin, A. (2003): An overview of biotechnology statistics in selected countries. DSTI/DOC(2003)/13. OECD Paris

2. Definition of biotechnology actors

Public Sector Research Organisations (PSROs):

A PSRO is an organisation performing research of which the source of funds is coming from other public organisations, and which is in public ownership or control. Research organisations of officially recognised charities or foundations, which raise the majority of their funds from the general public, are also considered as PSROs.

Biotechnology small and medium-sized enterprises (SME):

Biotechnology SME are biotechnology companies whose core activities are within the biotechnology definition given in section 1. They are performing biotechnology R&D. The category of SME is made up of enterprises which employ fewer than 250 persons and which have a turnover not exceeding 50 million € and/or an annual balance sheet total not exceeding 43 million €[11].

Large Firms (LF):

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

(1) They have developed also technological competencies in other fields than biotechnology. They are not dedicated to biotechnology but are users of biotechnology development. At the same time they may perform R&D activities at the frontier of biotechnological knowledge;

(2) They embody marketing, distribution, production and/or manufacturing competencies that prove central for other small firms lacking such competencies;

(3) Thus, their role is to commercialise new knowledge in biotechnology, embodied in new products.

11 European Commission (2003): Commission recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises. (2003/361/EC)

Annex 2: Policy Goals

In this section policy goals that are crucial for supporting the development of biotechnology are described in more detail. As discussed in chapter 2, these policy goals are a key component of the benchmarking concept.

Sub-area "development of the knowledge base and human resources"

- **Policy goal 1: the promotion of high-level basic research**

The promotion of high-level basic research for biotechnology is a key task of research policy which can be assisted by continuous monitoring of the development of the science base and implemented by top-down and/or bottom-up funding schemes. In addition, a suitable regulatory framework dealing adequately with ethical implications of biotechnology research and related safety issues is required.

- **Policy goal 2: the promotion of high-level industry-oriented and applied research in biotechnology**
- **Policy goal 3: the support of knowledge flow between scientific disciplines**

Measures to support the knowledge flow between scientific disciplines thereby assuring interdisciplinarity can be achieved in several ways that are not immediately associated with any specific policy area. Institutional arrangements such as the organisation of teaching and the organisation of research activities in public sector research organisations along interdisciplinary and not only disciplinary dimensions are crucial in this context.

- **Policy goal 4: securing the availability of qualified human resources**

The issue of availability of qualified human resources is a concern of education policy which needs to take care that the necessary skills to apply and develop biotechnology are covered adequately by graduate and post-graduate biotechnology training at higher education institutions.

Sub-area "Knowledge transmission and application"

- **Policy goal 5: To facilitate the transmission of knowledge from academia to the industry and its application for industrial purposes**

Mainly two policy areas can contribute to facilitate the transmission of knowledge from academia to industry. Firstly, a number of policy instruments which can be summarised as exploitation policies tackle e. g. the mobility of researchers, spin-off formation and the promotion of university industry interaction. Secondly, regulatory frameworks play a key role in the transmission of knowledge by establishing incentives to carry out research and to communicate research results, e. g. by setting conditions for obtaining

Intellectual Property Right (IPR) for biotechnology inventions. Finally, the regulatory framework is important for setting up intellectual property regimes for scientists working in public research institutions.

- **Policy goal 6: to incentive the adoption of biotechnology for new industrial applications**

Fiscal and demand-oriented policies can contribute to the promotion of the adoption of biotechnology for new industrial applications. Fiscal policies can create incentives for companies to invest in biotechnology adoption, while the demand-oriented policies can raise the awareness of the application of biotechnology in various industrial sectors by generating and disseminating information on potentials of biotechnology.

- **Policy goal 7: to assist firm creation**

The support of firm creation involves many different areas of policy. Firstly, education policy can assist universities in the design of curricula to promote the entrepreneurial spirit of scientists and spin-off formation. Secondly, policy for industrial development can supply resources and infrastructure for the R&D activities of start-ups. Fiscal measures can create incentives to promote venture capital investments. Finally, the regulatory framework has an influence on the availability of financial resources for companies (i. e. by creating adequate stock markets for technology companies which indirectly also promotes venture capital investments).

Sub-area "Market"

- **Policy goal 8: To monitor and to improve the social acceptance of biotechnology**

Demand-oriented policies can contribute to monitoring and improving of the social acceptance of biotechnology by supporting the continuous assessment of biotechnology impacts. An additional issue for demand policy is the support of dissemination and participation activities such as the organisation of workshops, seminars, citizen panels and consensus conferences, involving users and consumers of biotechnology.

- **Policy goal 9: to facilitate the access of biotechnology-based products to the market**

Various regulations play an important role in facilitating the market access of biotechnology-based products. Taking into account efficacy and safety issues, regulatory framework conditions for market access are in particular important for biopharmaceuticals and agro-food products. The challenge for regulations lies in striking a balance between assuring safety and efficacy and avoiding to set up unnecessary hurdles for market access.

- **Policy goal 10: to strengthen the economic sectors exploiting biotechnology**

Strengthening economic sectors exploiting biotechnology is influenced by various regulations which relate e. g. to price or reimbursement rules in the pharmaceutical sector or to the employment of qualified foreign staff. In addition, fiscal policies can contribute to strengthening these industries e. g. by creating tax incentives to promote innovative activities.

- **Policy goal 11: to keep and attract industrial leaders in these sectors**

Fiscal policies and regulations are key policy areas contributing to keep and attract industrial leaders in biotechnology-relevant sectors in the country.

Sub-area "Industry"

- **Policy goal 12: to support business investment in biotechnology R&D**

Policies for industrial development (such as subsidies, grants and loans for business R&D activities) can promote business investment in R&D. Fiscal policies can create incentives for companies and business investors to promote the private investment in biotechnology research.

- **Policy goal 13: to improve the competitiveness of biotechnology-based companies**

Policies to support the competitiveness of biotechnology companies involve the creation of attractive framework conditions to undertake innovation activities. In this context fiscal policies and regulation are key tools in the creation of such conditions. In addition, the education system can contribute to competitiveness by providing human capital with the necessary biotechnology knowledge and skills.

- **Policy goal 14: to exploit regional potentials and synergies**

The support of the exploitation of regional potentials and synergies relates to tasks of policies for industrial development. This includes e. g. facilitating the effective interaction of companies with the institutions in the regions. The support of clusters has emerged as wide-spread policy approach to this issue.

Annex 3: Methods

Annex 3 presents a detailed description of the methods used in the benchmarking. The first section (3.1) presents the policy questionnaire elaborated for retrieving policy information. Section 3.2 describes the methods used for analysing the policy questionnaire. The definition, sources and elaboration of output indicators, which aim at capturing possible outcomes of policy activities, are presented in section 3.3.

Annex 3.1: Policy questionnaire 2004

1. Education policies

1.1 Do public policies support educational institutions in developing programmes/curricula for biotechnology?

Yes ☐ No ☐

- If yes, please indicate the level of such courses/programmes available:

☐ Undergraduate (first) degree
☐ Master degree
☐ Doctorate

1.2 Do public policies support the inclusion of a module on Business Administration in university science degrees primarily related to biotechnology?

Yes ☐ No ☐

- If yes, please indicate the level of the courses/programmes including such modules:

☐ Master in biotechnology-related fields
☐ Doctorate in biotechnology-related fields

- Are the courses related to Business Administration compulsory?

Yes ☐ No ☐

- Do firms participate in the courses?

Yes ☐ No ☐

- What do the Business Administration modules cover?

☐ Basic knowledge of economic theory
☐ General knowledge of Business Administration
☐ Innovation Management

2. Research policies

2.1 Do public policies promote biotechnology research?

Yes ☐ No ☐

- If yes, please indicate

1) the *type* of instruments: General instruments to support research or specific instruments to support *biotechnology* research[12];
2) their *relative importance* within the whole set of public funding activities to support biotechnology research: (1 – not important to 5 – very important):

	Generic (G)					Biotechnology Specific (S)				
	1	2	3	4	5	1	2	3	4	5
Instruments for basic research	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Instruments for applied research	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Instruments supporting international mobility or researchers	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

2.2. Please estimate the share of the national public research and development (R&D) budget flowing into biotechnology in 2004 (or latest year available):

< 1.0 % ☐ 1.0-2.0 % ☐ 2.1-4.0 % ☐ 4.1- 5.0 % ☐ > 5.0 % ☐

12 In this questionnaire “generic“ instruments (G) refer to those policy instruments that do not discriminate between fields. “Biotechnology-specific“ instruments (S) are those instruments specifically designed to promote biotechnology. This terminology holds for questions 3 and 4 as well.

3. Exploitation policies

3.1 Do public policies support the commercial exploitation of research results from public research institutions and stimulate scientists to start a company?

Yes ☐ No ☐

- If yes, which of the following instruments are being used? Please, indicate if the implemented instruments are generic (G), biotechnology specific (S) or both:

	G	S
Establishment of technology transfer offices at universities	☐	☐
Financial support of scientists willing to apply for patents	☐	☐
IPR courses for entrepreneurial scientists	☐	☐
Grants for entrepreneurial scientists to write a business plan (i. e. for hiring experts and advisors)	☐	☐
Financial support (subsidies, loans, tax incentives etc.) for university spin-off formation	☐	☐
Others (please, specify):	☐	☐

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3.2 Do public policies provide incentives for collaborative research between industry and public sector research organisations?

Yes ☐ No ☐

- If yes, which of the following instruments are being used? Please, indicate if the implemented instruments are generic (G), biotechnology specific (S) or both:

	G	S
Grants for industrial research involving collaboration with public research	☐	☐
Grants for academic researchers to work in industry or vice versa (i. e. incentives for mobility between public and private research)	☐	☐
Incentives for industrial involvement in public research networks	☐	☐
Establishment of innovation centres/parks to ease university-industry interaction	☐	☐
Others (please, specify):	☐	☐

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4. Policies related to industrial development

4.1 Do public policies aim at improving the availability of financial capital and the access to private investment for high technology companies, including biotechnology?

Yes ☐ No ☐

- If yes, which of the following instruments are being used? Please, indicate if the implemented instruments are generic (G), biotechnology specific (S) or both:

	G	S
Direct subsidies for high tech companies (other than research grants)	☐	☐
Loans for high tech companies	☐	☐
Public equity investment in high tech companies	☐	☐
Tax benefits for business capital investors to promote investments in high tech companies	☐	☐
Other incentives than tax benefits for business capital investors (i. e. co-investment models where the government takes part of the risk)	☐	☐
Others (please, specify):	☐	☐

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4.2 Do public policies promote facilities and other forms of business support for start-ups?

Yes ☐ No ☐

- If yes, which of the following instruments are being used? Please, indicate if the implemented instruments are generic (G), biotechnology specific (S) or both:

	G	S
Establishment of infrastructure facilities (i. e. incubators, office rooms, laboratories and small-scale production facilities)	☐	☐
Consulting and advisory services in management issues (i. e. business plan elaboration, financing issues, etc.)	☐	☐
Consulting and advisory services in Intellectual property Rights (IPRs) issues	☐	☐
Consulting and advisory services in regulatory issues (other than IPRs)	☐	☐
Others (please, specify):	☐	☐

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4.3 Do public policies stimulate specifically biotechnology research in the industry?

Yes ☐ No ☐

- If yes, which of the following instruments are being used?

☐ Research grants for companies carrying out R&D
☐ Loans for companies carrying out R&D
☐ Tax benefits for companies carrying out R&D
☐ Others (please, specify):

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4.4 Do public policies support biotechnology clusters (i. e. regional concentration of public sector research organisations and/or companies and supportive institutions for innovation activities)?

Yes ☐ No ☐

- If yes, how many clusters are being supported currently by such policies?

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5. Fiscal policies

5.1 Are there in your country fiscal policy instruments (tax incentives) to promote innovation activities (such as firm creation, research and development, networking activities, training)?

Yes ☐ No ☐

- If yes, which organisations are the main target groups of such instruments (1 – not important to 5 – very important)?

	1	2	3	4	5
Spin-offs from public sector research organizations	☐	☐	☐	☐	☐
Small and Medium Enterprises (SMEs)	☐	☐	☐	☐	☐
Large firms (LFs)	☐	☐	☐	☐	☐
Private investors	☐	☐	☐	☐	☐

6. Regulation

6.1 In the design of regulations do the regulatory authorities in your country consider the issue of fostering innovation and creating attractive framework conditions for innovation processes?

Yes ☐ No ☐

- If yes, please indicate

1) to what extent the following issues are a priority for public authorities (1 – not important to 5 – very important)?

	1	2	3	4	5
Regulatory framework conditions to carry out fundamental research	☐	☐	☐	☐	☐
The intellectual protection (IP) of biotechnology inventions	☐	☐	☐	☐	☐
IP of research results form public research organisations	☐	☐	☐	☐	☐
Regulatory framework to hire qualified foreign staff	☐	☐	☐	☐	☐
Regulatory framework conditions for company creation (e. g. conditions for venture capital investment)	☐	☐	☐	☐	☐
Regulatory framework conditions for firm growth (e. g. access to financial markets)	☐	☐	☐	☐	☐

2) to what extent are the following industries and sectors considered in this context (1 – not important to 5 – very important)?

	1	2	3	4	5
Pharmaceuticals	☐	☐	☐	☐	☐
Chemicals	☐	☐	☐	☐	☐
Agro-Food	☐	☐	☐	☐	☐
Laboratory equipment and supplies	☐	☐	☐	☐	☐
Others (please, specify):	☐	☐	☐	☐	☐

7. Demand-oriented policies

7.1 Do public policies support initiatives to explore the benefits, costs and risks of the application of biotechnology?

Yes ☐ No ☐

- If yes, please indicate

1) which of the following activities and initiatives are carried out?

- ☐ Technology assessment studies
- ☐ Technology foresight studies
- ☐ Workshops or similar activities
- ☐ Establishment of centres/institutions focusing on technology assessment
- ☐ Others (please, specify):

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2) which of the following actors are involved in the supported activities?

- ☐ Policy-makers
- ☐ Companies
- ☐ Business interest non-government organisations
- ☐ Universities and research institutions
- ☐ Non-expert citizens
- ☐ Non-government organisations (NGOs)

3) which of the following issues are considered?

- ☐ Ethical aspects
- ☐ Legal aspects
- ☐ Economic effects
- ☐ Environmental effects
- ☐ Health aspects
- ☐ Gender issues
- ☐ Developing countries issues
- ☐ Consumer/patients preferences and public perception
- ☐ Future developments and applications in different economic sectors

7.2 Which of the following national policy instruments are implemented in your country to inform non-expert citizens about biotechnology and support their participation in public debates?

- ☐ Information initiatives with a biotechnology content
- ☐ Training activities for potential consumers of biotechnology-based products and services
- ☐ Consensus conferences or citizen panels on biotechnology-related issues
- ☐ Workshops to establish a dialog between policy-makers, companies, technical experts and non-expert citizens
- ☐ Others (please, specify):

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7.3 Do public policies stimulate the adoption of biotechnology for new industrial applications by companies that are not performing biotech R&D themselves?

Yes ☐ No ☐

- If yes, which of the following instruments are being used?

- ☐ Biotechnology information initiatives such as conferences and workshops for this type of companies
- ☐ Subsidies, loans and/or tax incentives for these companies to carry out demonstration and test projects involving the application of biotechnology
- ☐ Subsidies, loans and/or tax incentives for the full application of biotechnology in this type of companies
- ☐ Others (please, specify):

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8 Policy processes

A. Policy impact assessment

A.1 Has your country implemented specific mechanisms to assess the impacts of policy measures related to biotechnology?

Yes ☐ No ☐

- If yes, please indicate

1) at which stage do impact assessments take place?

☐ As soon as the need for policy intervention is recognised
☐ In the process of elaborating a new policy initiative
☐ After the policy initiative has been implemented

2) which institutions are involved in these procedures?

☐ Policy-makers directly involved in the elaboration of the policy initiative
☐ Policy-makers not directly involved in the elaboration of the policy initiative
☐ Industry and/or business interest non-government organisations
☐ Universities and research institutions
☐ Representatives of social groups and non-expert citizens

3) which issues and dimensions are considered in the impact assessment?

☐ Economic impact
☐ Social impact
☐ Environmental impact
☐ Ethical aspects
☐ Geographic dimension
 ☐ impact in different national regions
 ☐ impact within Europe
 ☐ impact beyond the European borders
☐ Temporal dimension
 ☐ short-term impact (0-5 years)
 ☐ mid-term impact (6-10 years)
 ☐ long-term impact (>10 years)
☐ Costs and benefits of alternative policy options to reach the same objective

B. Policy coordination

B.1 Are there formal mechanisms in your country to coordinate policy instruments promoting biotechnology?

Yes ☐ No ☐

- If yes, please indicate

1) which of the following mechanisms are being used?

☐ Establishment of an institutional forum/arena to guarantee coordination between regional and national policy instruments

☐ Establishment of a institutional forum/arena to guarantee horizontal coordination between policy areas (such as education, science, industry or infrastructure)

☐ Others (please, specify):

……………………………………………………………..............................

……………………………………………………………………………………

2) at which of the following levels does coordination take place?

☐ Level 1 (the highest level of co-ordination): An institution such as a council, cabinet or a ministry has the responsibility of 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).

☐ Level 2: Co-ordination among independent ministries occurs through an inter-ministerial institution where representatives from different ministries are involved. The institution can have advisory or policy-making functions.

☐ Level 3: A board (or similar arena) is responsible for operational co-ordination guaranteeing programme coherence among funding agencies, councils and/or academies.

C. Implementation of EC directives

Please assess the implementation process of the following EC directives in terms of speed and degree of controversy using a scale from 1 (very low) to 5 (very high)

	not yet implemented	Speed					Controversy				
		1	2	3	4	5	1	2	3	4	5
Patentability of Biotechnology Inventions 98/44/EC	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
The contained use of genetically modified micro-organisms 98/81/EC	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Marketing and release of genetically modified organisms 2001/18/EC	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Protection of workers from risks related to biological agents 2000/54/EC	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Thank you very much for your cooperation!

Annex 3.2: The analysis of the policy questionnaires

The questionnaire includes for each policy area between one and four master questions, which are further specified by sets of qualifying questions. In addition, a set of questions (included under point 8) referring to the policy-making process is included. The questionnaire provides 2 types of information about the national policy profiles. Firstly, a qualitative overview of policies implemented as sketched in section 1 of this annex. Secondly, the analysis of information from the policy questionnaire provides a quantitative assessment of the policy portfolio.

1. Qualitative assessment of the national policy implemented

The questionnaire includes for each policy area between one and four master questions which refer to policy instruments within each policy area. These master questions are further specified by sets of qualifying questions which are important for the quantitative assessment (see next section). Transferring the answers to the master questions to table A.3.2.1 results in the qualitative policy overview.

In addition to questions related to different policy areas the questionnaire contains a set of questions referring to the policy-making process. These are summarised under point 8 in table A.3.2.1.

Table A.3.2.1: Qualitative overview of biotechnology policies[13]

Policies	Implemented (yes / No)
1. Education	
1.1 biotechnology curricula	
1.2 business issues	
2. Research	
2.1 biotechnology promotion	
3. Exploitation	
3.1 entrepreneurship / spin-offs	
3.2 industry / Public Sector Research Organizations (PSROs)	
4. Industrial development	
4.1 availability of capital	
4.2 business support for start-ups	
4.3 industrial research (biotechnology specific measures)	
4.4 support for cluster development	

13 The numbers in the first column refer to the number of the master question in the questionnaire (see annex 3.1.a).

Table A.3.2.1 continued

Policies	**Implemented (yes / No)**
5. Fiscal	
5.1 tax incentives for innovation	
6. Regulation	
6.1 task innovation	
7. Demand	
7.1 explore benefits of biotechnology	
7.3 adoption of biotechnology	
8. Policy implementation processes	
8.A Impact Assessment	
8.B Coordination	

2. Quantitative assessment of the national policy implemented

The quantitative assessment of the policy profile draws on the analysis of the questionnaire where the different questions referring to the implemented policy measures can be classified according to the policy area the belong to and the policy goals they target. The analysis follows the scheme sketched in table A.3.2.2. The numbers included in the cells (preceded by a Q) correspond to the questions from the questionnaire. The dark grey cells refer to the questions regarding the biotechnology specific policy measures.

For quantifying the intensity of policy efforts in the seven policy areas explored in the questions 1-7, the answers to the qualifying questions (questions including a scale or different measures that can be selected if appropriate) within each master question (yes or no questions) are transferred into a five-point scale where 1 corresponds to the lowest and 5 to the highest level of policy activity. The calculation of these indicators for the individual qualifying questions is achieved in the following way:

- Question 1.1:
  - only undergraduate level: 1,
  - only master or only doctorate level: 2,
  - undergraduate and master degree: 3,
  - master degree and doctorate: 4,
  - all three levels: 5.
- Question 1.2:
  - master or doctorate: 1,
  - master and doctorate: 2,
  - compulsory master courses: 3,

  - compulsory doctorate courses: 4,
  - compulsory master and doctorate courses: 5.
- Question 2.1:
  - quantifying according to the scale in the question.
- Question 3.1:
  - quantifying according to the number of different measures in place,
  - only one measure corresponds to 1,
  - all measures correspond to 5.
- Question 3.2:
  - quantifying according to the number of different measures in place,
  - only one measure corresponds to 1,
  - all measures correspond to 5.
- Question 4.1:
  - quantifying according to the number of different measures in place,
  - only one measure corresponds to 1,
  - all measures correspond to 5.
- Question 4.2:
  - quantifying according to the number of different measures in place,
  - only one measure corresponds to 1,
  - all measures correspond to 5.
- Question 4.3:
  - quantifying according to the number of different measures in place,
  - only one measure corresponds to 1,
  - all measures correspond to 5.
- Question 4.4:
  - the highest number of clusters being supported among all included countries refers to 5,
  - lower numbers are transferred accordingly to the 1-5 scale.
- Question 5.1:
  - quantifying according to the 1-5 scale of the question.
- Question 6.1:
  - quantifying according to the number of different measures in place,
  - only one measure corresponds to 1,
  - all measures correspond to 5.

Table A.3.2.2: Quantitative assessment of biotechnology policy portfolio

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		Q.2.1.1 Q.2.1.1			Q. 6.1.2 Q. 6.1.3		
	2. To promote high level of industry-oriented (and applied) research		Q.2.1.2 Q.2.1.2					
	3. To support knowledge flow between scientific disciplines		Q.2.1.3 Q.2.1.3					
	4. To assure availability of human resources	Q.1.1						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			Q. 3.1 Q. 3.2. Q. 3.1 Q. 3.2		Q 6.1.5		
	6. The adoption of biotechnology for new industrial applications						Q 5.1.3	Q.7.3
	7. To assist firm creation	Q.1.2			Q. 4.1 Q. 4.2 Q. 4.1 Q. 4.2	Q 6.1.6	Q 5.1.1 Q 5.1.4	
Market	8. To monitor and improve the social acceptance of biotechnology							Q.7.1 Q.7.2
	9. To facilitate the introduction of new products					n.d.		
	10. To strengthen the economic sectors exploiting biotechnology					n.d.	Q 5.1.3	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)					n.d.	Q 5.1.3	
Industry	12. To encourage business investment in R&D				Q.4.3		Q 5.1.3 Q 5.1.2	
	13. To improve firm's competitiveness	Q.1.2				Q 6.1.2. Q 6.1.4. Q 6.1.6.	Q 5.1.3 Q 5.1.2	
	14. To exploit regional potentials				Q 4.4			

- Question 7.1 and 7.2:
  - quantifying according to the number of different measures in place,
  - only one measure corresponds to 1,
  - all measures correspond to 5,
  - only a combined indicator is calculated based on the average of the three sub-questions.
- Question 7.3:
  - quantifying according to the number of different measures in place,
  - only one measure corresponds to 1,
  - all measures correspond to 5.

If more than one question is included in the cell, the average value of the given questions is calculated. If no policy activities in a certain area are in place, this is indicated by zero. If no information is available, the correspondent cell will include the abbreviation "n.d.".

The questionnaire includes more information (such as the budget directed to the promotion of biotechnology, or the industry sectors being targeted by industrial policy, policy implementation) that is not considered for the quantitative analysis.

Annex 3.3: Output indicators: Definition, sources and elaboration

The output indicators used to map the achievement of policy goals are presented in table A.3.3.1 and discussed in more detail in this annex. Table A.3.3.2 summarises the extent to which data is available for the new Member States (NMS).

The output indicators selected are those which mainly provide truly comparable measurements of the same thing in different countries. The aim is to avoid using national data sources which may use widely differing definitions, measure the phenomenon in different ways and cover different time periods. However, such sources do not exist for all indicators.

As a first indicator we propose the number of biotechnology publications in a country per capita (**indicator 1** in table A.3.3.1). This indicator basically measures the scientific output of biotechnology in relation to the size of the country. As a measure of the impact of this output in the international scientific community we suggest to use the number of citations per biotechnology publication (**indicator 2**, table A.3.3.1).

Table A.3.3.1: Output indicators used to map national performance in biotechnology

	Output Indicator	Measure	Time frame and sources[14]
Knowledge base	1. Biotechnology publications	Number of biotechnology publications per thousand capita (ptC)	2002 or latest available date Science Citation Index, EUROSTAT
	2. Citations to biotechnology publications	Number of citations per BT publication	2002 or latest available date Science Citation Index
	3. PhD graduates in life sciences	Number of PhD graduates in life sciences per million capita (pmC)	2002 OECD, EUROSTAT
Knowledge transmission	4. Biotechnology patent applications	Number of BT patent applications ptC	2002 or latest available date EPAT, PCTPAT, EUROSTAT,
	5. Biotechnology SMEs[15]	Number of BT SMEs per million capita (pmC)	2002 or latest available date Ernst & Young Biotechnology Sector reports EUROSTAT

14 This information refers to the established data sources allowing the generation of comparable indicators among countries. See table A.3.3.2 for data availability in the new Member States.

15 See annex 1 for the relevant definition.

Table A.3.3.1: continued

	Output Indicator	Measure	Time frame and sources
Market	6. Responses to Eurobarometer 58.0 (2002) Questions 12, 13, 14	National average in responses to questions 12, 13, 14	Eurobarometer 58.0 (2002)
	7. Number of drug approvals	Number of drug approvals pmC	2002 or latest available date EMEA
	8. Field trials with GMO crops	Number of field trials with GMO crops pmC	2002 or latest available date Joint Research Centre (JRC), the Summary Notification Information Format Database (SNIF database).
	9. Volume of production in relevant industry sectors for biotechnology	Production in Purchasing Parity Standard (PPS) per capita	2002 OECD-STAN Database, EUROSTAT
Industry	10. Initial Public Offerings (IPOs) in Biotechnology	Number of IPOs in BT per number of BT companies	2002 or latest available date Ernst & Young Biotechnology Sector reports / the relevant Stock Exchanges
	11. Number of BT companies in the stock market	Number of BT companies in the stock market per number of BT companies	2002 or latest available date Ernst & Young Biotechnology Sector reports / the relevant Stock Exchanges
	12. Venture Capital (DVC) invested in biotechnology 12'. VC invested in high technology (HT) sectors	VC investments in BT in PPS per capita VC investments in HT in PPS per capita	2002 or latest available date EVCA, EUROSTAT
	13. Total VC investments	VC investments in PPS per capita	2002 or latest available date EVCA, EUROSTAT

These two indicators are based on data from the Science Citation Index (SCI), which is provided by the Institute for Scientific Information (ISI), however, at some cost. The advantage of using these two bibliometric indicators is that the indicators can be tailored very precisely to a chosen definition of biotechnology by using key words and SCI subject codes. In addition, such data is available for all countries. As a weakness of this indicator the English language bias of the SCI should be mentioned leading to a certain disadvantage of not English speaking countries.

The number of PhD graduates (**indicator 3**, table A.3.3.1) gives an indication of the ability of the national education system to provide a sufficient number of scientific personnel for biotechnology. PhD graduates refer to graduates of "Tertiary-type A" programmes (which in the terminology of the OECD include programmes for further education/theoretically based programmes) and advanced research programmes. Currently, this indicator is readily available for life sciences by using the OECD Education database. However, no such data is available for the specific area of biotechnology, so that the currently possible indicator only allows drawing conclusions on biotechnology with some caution.

Given the methodological and availability limitations for assessing knowledge transmission and application we suggest to use the number of patent applications in biotechnology per capita as an easily available indicator for assessing the transmission and application of knowledge (**indicator 4**, table A.3.3.1). We suggest using European patent applications for this purpose for two reasons. Firstly, access conditions to the European patent office are similar for all applicants, so that comparability of applications from different countries is facilitated. Secondly, since filing European rather than national patent applications requires quite some financial and human resources, it can be argued that these applications are a good indication for commercial interest and therefore relate directly to the policy goal of facilitating the transmission and application of biotechnological knowledge in industry. In addition, European patent applications must be published 18 months after notification, which allows to obtain current data. Data to construct this patent indicator are available for all countries from the European Patent Office. By using the same definition of biotechnology based on IPC (International Patent Classification) codes comparability across countries is high and reliable.

US patents are also very important for biotechnology. However, using US patents as indicators has the disadvantage that there is a delay in publication of patents since only granted patents and not patent applications are published.

A weakness of patent indicators is due to different attitudes towards patenting across countries. In addition, in some cases for strategic reasons higher or lower patenting activities can be observed which are not directly related to the issue of knowledge transfer and application.

As additional basic indicator for the application of biotechnology knowledge we suggest to use the number of biotechnology small and medium enterprises per million capita **(indicator 5,** table A.3.3.1). Annex 1 includes a detailed definition of these companies. Unfortunately, at present there is no consistent information available on the number of biotechnology firms in all Member States. National resources for this type of data should be explored. Most data rely on reports from consultancy firms, where the methodological basis for the presented data usually is not disclosed. Additionally, the

OECD has initiated biotechnology surveys in several OECD countries. To our knowledge all these possible sources suffer similar problems: lack of comparability due to different definitions being used, lack of complete coverage of the whole EU, lack of timeliness.

To assess the social acceptance of biotechnology responses to the Eurobarometer survey are the best indicators available. The Eurobarometer 58.0 (2002) survey on the public perception of biotechnology in Europe gathers information related to the social acceptance of biotechnology at the national and European level. The relevant questions to asses the social acceptance would be Q.12, Q.13, Q.14 **(indicator 6** in table A.3.3.1).

To asses the introduction of new biotechnology-based products to the market we propose two indicators. For the pharmaceutical sector the number of drug approvals by the EMEA (**indicator 7** in table A.3.3.1) seems suitable. For the food sector an appropriate indicator would be the number of field trials with genetically modified (GMO) crops (**indicator 8** in table A.3.3.1). Both indicators should be normalised to the size of the country (pmC).

Data for the indicator 7 is publicly available from the European Medicines Evaluation Agency. Data for the indicator 8 is available from different sources: for Europe from the Joint Research Center (JRC), the Summary Notification Information Format Database (SNIF database).

As indicator for the capacity of the national economies to fully benefit from the industrial application of biotechnology we propose the production volume (value of goods and/or services produced in a year) of the industrial sectors relevant for the application of (**indicator 9** in table A.3.3.1) per capita.[16] The STAN database from the OECD includes this data using SIC Codes to define the following economic sectors:

- Agriculture, hunting and forestry
- Food products and beverages
- Textiles
- Leather, leather products and footwear
- Paper and paper products
- Chemicals excluding pharmaceuticals

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16 To avoid bias in the transformation of the volume in a common currency (or purchasing power parity standard) the % volume of production relevant for biotechnology (instead of per capita volume) could be an alternative indicator.

- Pharmaceuticals
- Medical, precision and optical instruments, watches and clocks

Indicator 9 can be interpreted as the potential industrial demand for biotechnology, which can be supplied to a large extent by biotechnology firms.

As indicator for the performance and competitiveness of biotechnology companies we propose the number of initial public offerings (IPOs) by biotechnology companies listed in stock markets per biotechnology company (**indicator 10** in table A.3.3.1). IPOs occur in an advanced stage of development of the companies; accordingly we consider it as an indicator for the development phase of the companies in the industry. The data is publicly available directly from the Stock Markets and, for those countries with a relatively stark industry, in Ernst & Young Industry Reports.

Finally, as indicators to asses the conditions for enterprise financing in the biotechnology industry we propose the number of biotechnology companies in stock markets over the total number of biotechnology companies (**indicator 11** in table A.3.3.1), the total volume of venture capital investments (in the country) per capita (**indicator 13** in table A.3.3.1) and the volume of venture capital invested in domestic biotechnology companies per capita (**indicator 12** in table A.3.3.1). Data on venture capital is available from the European Venture Capital Association (EVCA). Please note that the data should refer to domestic investments, which include only venture capital being invested in the country.

To asses the achievement of policy goals in the sub-area "industry" the benchmarking should include biotechnology-specific data. However, if biotechnology-specific data is not available, these indicators (especially indicator 12) could be gathered more generally to try to cover the high-technology sector.

Table A.3.3.2: Availability of output indicators for the new Member States (NMS)

	Output Indicator	Possible Sources[17]	Availability in NMS
Knowledge base	1. Biotechnology publications	Update of BT Innovation Scoreboard (?) Science Citation Index	The data can be gathered through online databases (until 2002)
	2. Citations to biotechnology publications	Update of BT Innovation Score Board (?) Science Citation Index	The data can be gathered through online databases (until 2002)
	3. PhD graduates in life sciences	OECD Education Database	Czech Republic (2002) Hungary (2002) Poland (2002) Slovakia (2002) Estonia (2003)*
Knowledge transmission	4. Biotechnology patent applications	Update of BT Innovation Scoreboard (?) Online Databases	The data can be gathered through online databases (until 2002)
	5. Biotechnology SMEs		
Market	6. Responses to Eurobarometer Questions 12, 13, 14	Next Eurobarometer (?)	Currently no data. In the future available for all NMS as long as they are included in the survey.
	7. Number of drug approvals	EMEA	Available for all NMS as long as they have applied for approvals of biomedicines (currently no applications)
	8. Field trials with GMO crops	Joint Research Center (JRC), the Summary Notification Information Format Database (SNIF database).	Available for all NMS as long as they have applied for SNIFs (currently only one application from Poland)
	9. Volume of production in relevant industry sectors for biotechnology	OECD-STAN Database	Czech Republic (2000-2001) Hungary (1995-2002) Poland (1995-2002) Slovakia (1995-2001) Estonia (2002)*

* Currently available from national sources only.

17 Only sources guaranteeing comparability across countries.

Table A.3.3.2: continued

	Output Indicator	Sources	Availability in NMS
Industry	10. Initial Public Offerings (IPOs) in Biotechnology		
	11. Number of BT companies in the stock market		
	12. Venture Capital (DVC) invested in biotechnology 12'. VC invested in high technology (HT) sectors	EVCA Annual Reports	Hungary (2002) Poland (2002) Czech Republic (2001-2002) Hungary (2001-2002) Poland (2001-2002) Slovakia(2001-2002)
	13. Total VC investments	EVCA Annual Reports and other EVCA documentation[18]	Czech Republic (2001-2002) Hungary (2001-2002) Poland (2001-2002) Slovakia(2001-2002)

18 In other free available sources from EVCA focusing on Central and Eastern Europe there are data available for all new Members except for Malta.

Annex 4: Country profiles

The country profiles integrate biotechnology policy profiles of the European Member States participating in the first round of the Biotechnology Policy Benchmarking. The information draws on information provided by the different members of the Commission Biotech Network who have completed the Policy Questionnaire 2004 and provided additional information relevant for the benchmarking exercise (in the period from November 2004 to mid January 2005).

Additionally, for the old Member States, the USA and Canada, biotechnology policy profiles for the period 1994/95 and output indicators for the year 2002 (or data for the latest year available) are included. These data have been elaborated by the project team in order to validate the benchmarking concept using historical data (as requested by the tender specifications of the European Commission). The availability of policy profiles from the mid 1990s and the output data from 2002 allows deriving conclusions on the effectiveness of policy, since it can be expected that potential policy effects should be detectable by the output indicators after a period of 5 to 7 years. In the case of the new Member States, such a historical analysis was not intended within this project.

A detail description of the methodological issues related to the tables presented and the elaboration of the indicators can be found in annex 3. Additionally, tables with the raw data of the indicators have been included in annex 5.

1 Austria

Policy profile of 1994/95

The Austrian policy profile indicates that in the period 1994/95 the policy activity in the relevant for biotechnology was rather weak. Most policy initiatives targeted policy goals related to the improvement of the knowledge-based biotechnology and human resources. A relatively weak body of policy measures targeted knowledge transmission, the market side and industrial development of biotechnology.

Regarding the policy areas engaged in promoting biotechnology, according to the available information research policy followed mainly generic approaches to support the biotechnology knowledge base. Policies aiming at exploitation of scientific results combined both generic and specific approaches although at a rather low level. The same holds for industrial development with the exception of policies to encourage business investment in R & D which achieved a rather high indicator value. There were no regulatory approaches and fiscal measures to foster innovation in biotechnology. On the demand side public policy was engaged in monitoring and improving the social acceptance of biotechnology.

Regarding the output indicators in 2002, those related to the knowledge base and to the level of human resources are slightly below (in the case of publications and citations) or well below the European average. Indicators of knowledge transmission are at about the European average. On the market side the output indicators are all below the European average. Drug and field trials indicate a very low biotechnology activity in Austria. The biotechnology acceptance index is below the European average as well. On the other hand the production indicator shows that in principle the size of the industry which could adopt biotechnology is interesting. Indicators for industrial development again present a weak performance.

Concerning the relation between policy goals, policy activities and output indicators, which provide information on the achievement of policy goals, some first preliminary conclusions can be drawn:

- With respect to the market and industrial development the weak policy activity seems to be correlated with output indicators below the European average.
- A similar relation seems to hold for the creation and development of the knowledge base and human resources for biotechnology. Both, output indicators and policy engagement are weak. Only the generic policy activities aiming at promoting a high level of industry-oriented and applied research seemed to have some effects on the knowledge transmission. The average value of knowledge transmission output

indicators can reflect that policy activities promoting industry-oriented research seemed to pay off at least to some extent.

Policy profile 2004

The Austrian policy profile for the year 2004 indicates strong policy engagement to cover all aspect of the biotechnology innovation system and to reach the relevant policy goals for the development and commercialisation of biotechnology. According to the information available more than 5 % of the national public R&D budget was invested in the promotion of biotechnology. Especially the development of the knowledge base and the provision of human resources seem to be the target of policy action in 2004.

Regarding the policy areas active in supporting the biotechnology innovation system, education, research and fiscal policy seem to be the most active resorts with a combination of generic and biotechnology-specific instruments. Fiscal policy seems to play a strong role in the policy agenda. Fiscal incentives are in place in all relevant processes of the biotechnology innovation system. Only fiscal incentives for private investors, which might be relevant for supporting firm creation and growth, are missing.

The policy area targeting industrial development appears to be quite weak, with only generic instruments to support firm creation. The same trend can be recognised in the stimulation of the demand for biotechnology. These two areas present important gaps.

Regarding the regulatory issues, policy action seems to be aware of the importance of the framework conditions for biotechnology. However, the regulatory framework seems to be concerned mainly concerned with the issues of knowledge transmission while regulatory issues concerning research, market and industrial process are disregarded.

Regarding the policy implementation processes, the Austrian policy system does not include any type of impact assessment in the policy design process. Coordination mechanisms are in place to guarantee horizontal coordination between policy areas (such as education, science, industry or infrastructure). These mechanisms are strongly institutionalised. In what concerns the implementation of biotechnology relevant EC Directives Austria has not implemented jet the directive for the patent of biotechnology inventions. Further more, the process of implementing the directive of marketing and release of genetically modified organisms has been very slow and controversial. This rigidity of the system in establishing framework conditions for biotechnology does not contribute to the exploitation of biotechnology.

Given the policy profile for 2004, if policy is effective, we might expect a positive development of the knowledge base of the Austrian biotechnology innovation system in the next three to five years and an improvement of the relevant output indicators for the knowledge base and for knowledge transmission. The development at the market and industrial level might be slower. The framework conditions do not seem to be appropriate for a positive trend in the marketing of biotechnology-based products.

Dynamic changes in the policy profile

The Austrian policy profiles of 1994/95 and 2004 present a quite different level of policy engagement in the promotion of biotechnology. The Austrian government seems to have radically changed its strategy towards the support of biotechnology in all areas of the biotechnology innovation system. The strongest changes appear in research and education policy where a whole range of generic and biotechnology-specific measures seemed to have been implemented in recent years. According to the information available fiscal policy has turned to be a key policy instrument. In the areas of industrial development, regulation and demand the policy profile still presents important gaps.

Austria 1994/95

	Policy goals	Policy Area							Output Indicators
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	**2002** *or latest available year* **100 = EU Average**
Knowledge base and human resources	1. To promote high level of biotechnology basic research		**2** **0**			**0**			O1. Publications **88** O2. Citations **116** O3. Graduates **53**
	2. To promote high level of industry-oriented (and applied) research		**5** **0**						
	3. To support knowledge flow between scientific disciplines		**1** **0**						
	4. To assure availability of human resources	**0**							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			**2** **2**		**0**			O4. Patents **102** O5.Companies **109**
	6. The adoption of biotechnology for new industrial applications						**0**	**0**	
	7. To assist firm creation	**0**			**1** **1**	**0**	**0**		
Market	8. To monitor and improve the social acceptance of biotechnology							**3**	O6. Accept. Index[19] **100,89** O7. Drug approvals **0** O8. Field Trials **11** O9. Production **81**
	9. To facilitate the introduction of new products					**0**			
	10. To strengthen the economic sectors exploiting biotechnology						**0**		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						**0**		
Industry	12. To encourage business investment in R&D				**3**		**0**		O10. IPOs **0** O11. Pub. Comp. **0** O12. VC in Biotech **12** O13. Venture Cap **27**
	13. To improve firm's competitiveness	**2**				**0**	**0**		
	14. To exploit regional potentials				**0**				

19 EU Average is 100,29. See annex 5.

Austria 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 / 5			1		
	2. To promote high level of industry-oriented (and applied) research		5 / 4					
	3. To support knowledge flow between scientific disciplines		3 / 3					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 / 2		3		
	6. The adoption of biotechnology for new industrial applications						4	0
	7. To assist firm creation	3			3 / 0	3	2	
Market	8. To monitor and improve the social acceptance of biotechnology							3
	9. To facilitate the introduction of new products					2		
	10. To strengthen the economic sectors exploiting biotechnology						4	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						4	
Industry	12. To encourage business investment in R&D				0		5	
	13. To improve firm's competitiveness	3				2	5	
	14. To exploit regional potentials				1			

2 Belgium

Belgium is a federal state and includes three regions (Wallonia, Flanders and Brussels Capital Region). Science, technology and innovation policies are developed and implemented at the federal and regional levels. In the Belgian policy profiles, relevant public policies for both the federal and the regional level are included.

Policy profile of 1994/1995

The Belgium policy profile indicates rather extensive policy activities in the seven policy areas with respect to almost all policy goals. Exceptions are policies aiming at supporting the knowledge flow between scientific disciplines and activities to exploit regional potentials.

On the output side, most indicators show performance levels above the European average. This could indicate that most policy goals have been achieved due to the support provided by the extensive policy activities in almost all policy areas.

Policy profile of 2004

The policy profile for Belgium in 2004 shows a strong focus on public policies supporting biotechnology research. Basic and applied research are equally considered as important and are promoted by generic and biotechnology specific policy instruments. Instruments to support international mobility of researchers are less relevant in this set of research policies. The importance of biotechnology research in public policies is also reflected by the relatively high share of the national public R&D budget spent on biotechnology: more than 5%.

Biotechnology education programmes are supported at both, undergraduate and master degree levels and are dedicated to natural sciences only; there is no public support for business administration courses in the university curriculum.

The 2004 policy profile shows that only generic instruments have been implemented for supporting and promoting the commercial exploitation of research results from public research organisations and the industrial development in biotechnology. These instruments support the establishment of technology transfer offices at universities and innovation centres to promote university-industry interaction. In addition, there are grants to support industrial research involving collaboration with public research. There are no public policies aiming at improving the availability of financial capital. However, high technology companies are supported through public consulting and advisory services in management issues. Two biotechnology clusters are supported by public policies and companies carrying out R&D can make use of loans and tax benefits for their R&D activities. Nevertheless, there are no public policies stimulating companies that are not performing biotechnology R&D themselves to adopt biotechnology for new industrial applications.

Belgium has several tax incentives to promote innovation, mainly targeting spin-offs and SMEs. However, fostering innovation is not taken into account when designing regulations. Regarding the implementation of EC directives, only the directive about the contained use of genetically modified micro-organisms (GMOs) has been implemented so far. The directives that are related to the patentability of biotechnology inventions and to the marketing and release of GMOs have not been implemented yet; they are considered as very controversial. The directive regarding the protection of workers is not considered as controversial and will probably soon be implemented.

On the demand side, Belgium has initiated activities to stimulate a dialogue between various stakeholders and to discuss the benefits, costs and risks of biotechnology. In these activities, policy-makers, non-expert citizens and NGOs are involved, but research organisations and industry are not included. To inform citizens, consensus conferences and workshops promoting a dialog between the various stakeholders are organised. Many different issues are taken into account, except for legal aspects, gender issues and future development and applications of biotechnology.

Regarding the policy processes, Belgium organises ad-hoc inter-ministerial workshops and meetings to coordinate biotechnology policies. There are no mechanisms installed to assess the impact of the various policy measures.

Dynamic changes in the policy profile

The 2004 policy profile for Belgium differs from the 1994/1995 profile especially regarding public policies targeting knowledge transmission, commercialisation and industrial development. In the 2004 profile almost no policies exist that support and promote the transmission of knowledge, commercialisation and industrial development of biotechnology. The only policy goal mentioned is encouragement of business investment in R&D (policy goals 12) through loans and tax benefits for companies carrying out R&D. The presence and relevance of generic and biotechnology specific research policies has not really changed in the last 10 years.

The 2004 profile is based on data provided by the Belgian expert which was asked for this task by the Belgian government. He has experience in the Belgian biotechnology industry (as the secretary general of EuropaBio and the a. i. secretary general of the Belgian biotechnology industry association). The Belgian expert and the POLYBENCH project team agreed that differences between the two profiles can be based on differences in interpretation of specific instruments (for instance the VIB instrument) and a possibly more normative assessment given by the Belgian expert due to his industry background. In addition, although the expert tried to present a complete overview of the policy instruments being implemented, the complexity of Belgian policy making and implementation makes it very difficult to give such an overview in a comprehensive form for analysis.

Belgium 1994/1995

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators: Type Index (100 = EU Average)
Knowledge base and human resources	1. To promote high level of biotechnology basic research		3 5			n.d.			O1. Publications **118** O2. Citations **117** O3. Graduates **128**
	2. To promote high level of industry-oriented (and applied) research		3 5						
	3. To support knowledge flow between scientific disciplines		1 0						
	4. To assure availability of human resources	4							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 4		n.d.			O4. Patents **166** O5.Companies **99**
	6. The adoption of biotechnology for new industrial applications						4	1	
	7. To assist firm creation	n.d.			3 3	n.d.	2		
Market	8. To monitor and improve the social acceptance of biotechnology							n.d.	O6. Accept. Index[20] **100,59** O7. Drug approvals **0** O8. Field Trials **193** O9. Production **128**
	9. To facilitate the introduction of new products					n.d.			
	10. To strengthen the economic sectors exploiting biotechnology						4		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						4		
Industry	12. To encourage business investment in R&D				0		4		O10. IPOs **46** O11. Pub. Comp. **44** O12. VC in Biotech **206** O13. Venture Cap **69**
	13. To improve firm's competitiveness	n.d.				n.d.	4		
	14. To exploit regional potentials				1				

20 EU Average is 100,29.

Belgium 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		4 4			0		
	2. To promote high level of industry-oriented (and applied) research		4 4					
	3. To support knowledge flow between scientific disciplines		2 2					
	4. To assure availability of human resources	3						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			1 0		0		
	6. The adoption of biotechnology for new industrial applications						1	0
	7. To assist firm creation	0			1 0	0	3	
Market	8. To monitor and improve the social acceptance of biotechnology							2
	9. To facilitate the introduction of new products					0		
	10. To strengthen the economic sectors exploiting biotechnology						1	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						1	
Industry	12. To encourage business investment in R&D				3		3	
	13. To improve firm's competitiveness	0				0	3	
	14. To exploit regional potentials				1			

3 Czech Republic[21]

Policy profile of 2004

Even if the Czech policy profile is incomplete, secondary sources can be used to portray the Czech situation. Czech Republic has a relative strong knowledge base and human resources training with respectively 78 universities and research institutes and around 30,000 students in biology, chemicals and pharmaceutical-related disciplines. Private sector does exist in the Czech Republic. 36 biotechnology companies including private investors such as Baxter and Lonza as well as 42 pharmaceutical-related companies, 20 food and 18 environmental-related firms. The pharmaceutical industry has been privatised and it is in a relatively good position in EC. There is a long tradition of private support for R&D.

The Czech policy profile shows that in 2004 national and regional public authorities have mainly installed policies that support biotechnology research, education in biotechnology as well as firm installation and development.

The Czech government as well as regional authorities invest to develop biotechnologies in different ways:

(1) Supporting public research organisations to perform research and to train students;

(2) Harmonisation of patent policy in Czech republic ((Act n° 597/1992);

(3) All European directives related to biotechnology (patentability of biotechnology inventions, use of GMOs, commercialisation of GMOs, protection of workforce) and standards (GMP, GLP and GCP) have been adopted;

(4) Cluster policy around Praha and Brno.

21 Due to the difficulties in identifying a contact person with a background on biotechnology policy issues for the Czech Republic, the content of the policy profile 2004 should be treated as very preliminary.

Czech Republic 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		3 / 0			0		
	2. To promote high level of industry-oriented (and applied) research		3 / 0					
	3. To support knowledge flow between scientific disciplines		4 / 0					
	4. To assure availability of human resources	4						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			0 / 0		0		
	6. The adoption of biotechnology for new industrial applications						0	0
	7. To assist firm creation	0			0 / 0	0	0	
Market	8. To monitor and improve the social acceptance of biotechnology							3
	9. To facilitate the introduction of new products					0		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				0		0	
	13. To improve firm's competitiveness	0				0	0	
	14. To exploit regional potentials				n.d.			

4 Denmark

Policy profile 1994/1995

The Danish policy profile in the mid 1990s presents a rather sharp division between market-oriented policies and policies oriented towards industrial development (where only low level of policy activity can be observed) and policies aiming towards knowledge base and human resources and knowledge transmission (where in at least some policy areas rather intensive activities could be identified). Regarding the policy areas, regulation and fiscal measures seemed to be neglected areas in the mid 1990s according to the information available.

On the output side, with indicators for 2002 (or the latest available year) Denmark performs well above the European average with respect to most indicators. Exceptions are the market indicators. For instance, the indicator O 9 (which captures the per capita size of the Danish industry sectors which could provide a market for biotechnology) is below the European average. On the industry side the indicator O 13 presents a weak venture capital investment per capita compared to the European average. Finally, the human resources indicator O 3 is below the European average as well.

Concerning the relations between policy goals and policy areas in 1994/95 and output indicators of the innovation system in 2002 we put forward the following observations:

- The rather high activities in specific research policies aiming to support policy goals 1 and 2 seem to be positively related to the very high level of publication output (and above average citations output).
- A similar observation can be made for policy goals 5 and 7 where also rather high specific policy activity goes along with very high patent and company output indicators.
- On the market side we observe that a rather high performance seems not to be driven by intensive policy activities in the respective areas.
- A similar situation seems to be the case in industrial development. However we should point out that data on the policy input which would be required to support these observations is missing.

Policy profile 2004

In 2004 Denmark dedicates more than 5 % of its national R&D budget to biotechnology. Regarding the policy goals targeted by the Danish policy system, policy engagement seems to be directed to the improvement of basic and applied research (policy goals 1 and 2) and to the monitoring and improvement of the social acceptance (policy goal 8). In general terms the policy goals related to the knowledge base and the transmission of knowledge seem to receive more attention than the policy goals targeting market performance of biotechnology products and services and industrial development. Indeed, the supply side of the markets of biotechnology-based products and services is one of the aspects of the biotechnology innovation system where the policy system does not seem to focus on (which is targeted by the goals 9, 10 and 11).

Regarding the policy instruments being implemented, the profile captures a quite equilibrated engagement of all policy areas contributing to the achievement of the policy goals. Only the area of education presents some important gaps in what concerns the supply of human capital with the appropriate combination of skills in business issues and sciences. Additionally, demand policy (which includes instruments to promote the adoption of biotechnology for new industrial applications) seems to be neglecting the importance of industrial demand (especially from companies that do not have capabilities to carry out research and development activities) for the diffusion of biotechnology applications.

The design and implementation of biotechnology policy in Denmark seems to be highly coordinated. The Ministry of science, technology and innovation coordinates the policy instruments promoting biotechnology. However, according to the information available, activities assessing the impacts of policy measures do not exist at the moment.

Regarding the implementation of EC directives, Denmark has been very fast in integrating all biotechnology relevant directives in the national law. Two directives (patentability of biotechnology inventions and the marketing and release of GMOs) have been controversial.

Dynamic changes in the policy profile

In what concerns the development of the policy intervention along the 1990s, according to the information available and captured in the policy profiles we can highlight the persistent commitment of the Danish policy system to the promotion of the biotechnology knowledge base with both, generic and biotechnology-specific instruments. Today the generic instruments seem to have more weight than biotechnology-specific instruments. An important development seems to be the policy engagement to improve the framework conditions for innovation through the regulatory framework. Especially the conditions to carry out fundamental research, but also conditions for innovation in the pharmaceutical and agro food sectors seem now to be present in the portfolio of regulatory institutions. Similarly now fiscal measures to promote industrial innovation exist.

The policy profile seems to be adequate to maintain the traditionally strong biotechnology knowledge base of the Danish biotechnology innovation system, even though the measures to guarantee the availability of human resources for industry activities are still missing. Further more, the policy engagement in promoting innovation through the regulatory framework and fiscal measures should further stimulate biotechnology-based innovation in the industry sector.

Denmark 1994/95

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators: 2002 *or latest available year* 100 = EU Average
Knowledge base and human resources	1. To promote high level of biotechnology basic research		n.d. 5			0			O1. Publications **190** O2. Citations **110** O3. Graduates **85**
	2. To promote high level of industry-oriented (and applied) research		n.d. 4						
	3. To support knowledge flow between scientific disciplines		1 3						
	4. To assure availability of human resources	n.d.							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 2		0			O4. Patents **317** O5.Companies **207**
	6. The adoption of biotechnology for new industrial applications						0	0	
	7. To assist firm creation	n.d.			4 3	0	0		
Market	8. To monitor and improve the social acceptance of biotechnology							4	O6. Accept. Index[22] **101,18** O7. Drug approvals **1190** O8. Field Trials **134** O9. Production **13**
	9. To facilitate the introduction of new products					0			
	10. To strengthen the economic sectors exploiting biotechnology						0		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0		
Industry	12. To encourage business investment in R&D				0		0		O10. IPOs **211** O11. Pub. Comp. **202** O12. VC in Biotech **279** O13. Venture Cap. **56**
	13. To improve firm's competitiveness	n.d.				0	0		
	14. To exploit regional potentials				n.d.				

22 EU Average is 100,29. See annex 5.

Denmark 2004

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 4			5		
	2. To promote high level of industry-oriented (and applied) research		5 4					
	3. To support knowledge flow between scientific disciplines		4 3					
	4. To assure availability of human resources	3						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 2		4		
	6. The adoption of biotechnology for new industrial applications						3	1
	7. To assist firm creation	0			3 3	4	2	
Market	8. To monitor and improve the social acceptance of biotechnology							5
	9. To facilitate the introduction of new products					3		
	10. To strengthen the economic sectors exploiting biotechnology						3	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						3	
Industry	12. To encourage business investment in R&D				3		4	
	13. To improve firm's competitiveness	0				4	4	
	14. To exploit regional potentials				1			

5 Estonia

Policy profile of 2004

Among the seven policy areas, currently education policies to support the biotechnology-specific knowledge base are very important in Estonia. However, there is no stimulation of the integration of business issues into biotechnology education schemes. With respect to research policies, the actual policy profile of Estonia exhibits rather intensive policy activities, which are predominantly of a generic nature. Only in the case of supporting basic research for biotechnology some specific initiatives are in place. In general, biotechnology is considered as an important focus of R&D policies in Estonia as indicated by the high share of the national public R&D budget (well above 5 %) flowing into biotechnology. Exploitation policies and policies oriented towards industrial development are on a medium activity level in Estonia. All activities are generic. Presently there are no specific regulation policies or fiscal measures aiming at supporting biotechnology in Estonia. On the demand side, few activities are in place to improve social acceptance of biotechnology. These comprise mainly information measures in the context of the Estonian Human Genome Project. Some other information activities aim at facilitating the adoption of biotechnology for new industrial applications.

Considering the fourteen policy goals which are crucial for the main biotechnology areas it becomes obvious, that the current focus in Estonia is on supporting knowledge generation for biotechnology. This focus reflects the early stage of the development of biotechnology in Estonia. Accordingly, all policy goals that are relevant for the market and for industrial development presently play no major role in the Estonian profile. It should be noted however, that government's innovation and entrepreneurial policies are directed towards creating a general supportive climate for entrepreneurship and industrial development in Estonia, which is also beneficial to biotechnology companies.

Concerning policy processes in Estonia, few specific mechanisms to assess the impacts of policy measures related to biotechnology have been implemented. These assessments are performed in the process of elaborating new policy initiatives and include policy-makers directly involved in the elaboration of the policy initiatives, industry- and business-interested non-government organisations as well as universities and research institutions. The impact assessments focus on economic issues and have mainly a domestic perspective. Short-term impacts up to five years are considered.

There are no formal mechanisms in Estonia to coordinate policy instruments promoting biotechnology. With respect to the implementation of EC directives, all directives relevant for biotechnology have been implemented with no controversy at a very high speed.

Estonia 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 / 1			0		
	2. To promote high level of industry-oriented (and applied) research		4 / 0					
	3. To support knowledge flow between scientific disciplines		2 / 0					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			3 / 0		0		
	6. The adoption of biotechnology for new industrial applications						0	1
	7. To assist firm creation	0			3 / 0	0	0	
Market	8. To monitor and improve the social acceptance of biotechnology							2
	9. To facilitate the introduction of new products					0		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				0		0	
	13. To improve firm's competitiveness	0				0	0	
	14. To exploit regional potentials				n.d.			

6 Finland

Policy profile of 1994/95

The Finnish policy profile of the mid 1990s indicates that most activities were concentrated on supporting the knowledge base and human resources as well as knowledge transmission. On the market side and on the side of industrial development we find only low activities or information on relevant policy initiatives is not available. All four policy goals related to the improvement of the knowledge base in human resources were supported by rather intensive specific research and education policies. This was also the case for exploitation policies supporting policy goal 5 and to a lower degree to policies aiming at assisting firm creation.

On the output side Finland outperforms the European average with respect to most indicators. An obvious exception is the market indicator O7 related to drug approvals (which reflects however, the absence of a strong pharmaceutical industry in Finland) and the biotechnology acceptance index (O6), which does not reach the European average either. A little surprising seems to be the below European performance in terms of graduates in life sciences.

With respect to the relation between policy goals, policy areas and output indicators due to lacking information about policy activities related to market and industry preliminary conclusions can only be drawn for the first two areas – knowledge base and human resources; knowledge transmission. In these areas the mainly above average performance indicators suggest that the rather strong policy initiatives in the respective areas have been effective in achieving the respective policy goals. An open question remains the mismatch between a high level of education policy initiatives and a rather low level of graduates in life sciences.

Policy profile of 2004

The Finnish policy profile of 2004 indicates that among the seven policy areas by far most activities are concentrated on research policies, where generic and specific instruments for supporting basic research, applied research and international mobility of researchers are considered as most important. The high significance of research policies is underlined by the rather high share of the national public R&D budget flowing into biotechnology. In 2004 this share was between 4.1 and 5.0 %.

Besides research policies and education, exploitation and industrial development policy play an important role in the Finnish policy profile. In the case of exploitation, the Finnish policy approach prefers generic instruments rather than specific measures. A similar situation holds true for industrial development where instruments to assist firm creation are of generic nature. Regulatory approaches are relevant for supporting the knowledge base, for knowledge transmission and for industrial development. The regulatory approaches to supporting biotechnology are oriented mainly towards pharmaceuticals and diagnostics. Chemicals and agro food products are other product groups where supportive regulatory measures play a role. On the market side, regulation policies are not relevant in Finland. There are no specific fiscal measures to support biotechnology in Finland. Some demand-oriented activities have been implemented aiming to support the adoption of biotechnology for new industrial applications and also to monitor and improve the social acceptance of biotechnology.

Looking at the 14 policy goals we observe that all policy goals related to the knowledge base and human resources are supported by various and intensive policy activities. In the knowledge transmission field a focus of the Finnish policy approach seems to be on the facilitation of knowledge transmission from academia to industry, while the adoption of biotechnology for new industrial applications is supported only by rather low policy activity. There are some measures to support firm creation mainly related to education and industrial development policies. Policy goals to support market development of biotechnology are not in the focus of the Finnish policy approach. Only some activities in the area of social acceptance of biotechnology can be observed. Concerning industrial development, there is some policy support from education and regulation policies to improve firm's competitiveness, and industrial development policies aim at supporting business investment in R&D. There are no specific policies to support regional biotechnology clusters in Finland. Even though five biocentres have been established in different regions, they network strongly with each other.

Concerning policy processes, Finland has not implemented any specific mechanisms to assess the impacts of policy measures related to biotechnology. Policy coordination, on the other hand, is an issue in the Finnish policy profile related biotechnology in a sense that there are formal mechanisms to coordinate policy instruments promoting biotechnology. These instruments comprise networking different ministries. The coordination takes place in a way that an inter-ministerial institution is established where representatives from different ministries are involved.

The EC directives on patentability of biotechnology inventions (1998/44/EC), the contained use of genetically modified microorganisms (1998/81/EC), on marketing and release of genetically modified organisms (2001/18/EC), and on protection of workers from risks related to biotechnological agents (2000/54/EC) all have been implemented in Finland. The speed of implementation for the patent directive was very high. The contained use directive and the protection of workers directive were also implemented at a high speed, while the implementation process of the marketing and release directive proceeded more slowly. The degree of controversy in Finland, in the context of implementation of these directives, was very low in the case of the protection of workers directive and low in the case of the patent directive. There was some controversy in the context of the implementation of the contained use and the release directives.

Dynamic changes in the policy profile

Comparing the Finnish policy profiles between 2004 and the mid 1990s reveals that presently even more emphasis is put on policies to support the knowledge base and human resources for biotechnology. We also observe more intensive efforts to support knowledge transmission. Additionally, there seems to be a certain shift in this area from specific to generic policies. Due to lacking data about the mid 1990s policy profile, only few observations can be made on changes in market-related and industrial-development-related policies. In general, there seems to be some intensification of policy efforts related to these two areas. The policy emphasis seems to be changing from the promotion of science and technology towards the promotion of innovation.

Considering the relation between the current policy profiles and future performance of the Finnish biotechnology innovation system it could be expected, that the strong policy activity in supporting the knowledge base and human resources will contribute to maintaining the above average performance of Finland in terms of publications. Likewise, the intensified policy activities targeting knowledge transmissions might contribute to sustain the favourable position in terms of patent application and biotechnology companies.

The comparison between the mid 1990s policy profile and the current output indicators revealed a mismatch between policy effort and output in particular for policy goal four – availability of human resources –, where the number of graduates was well below the European average. It will be interesting to observe whether the even increased policy activities towards improving human resources for biotechnology will lead to an improvement of this output indicator in the future.

Finland 1994/95

	Policy goals	Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators: 2002 *or latest available year* 100 = EU Average
Knowledge base and human resources	1. To promote high level of biotechnology basic research		4 2			n.d.			O1. Publications **142** O2. Citations **120** O3. Graduates **62**
	2. To promote high level of industry-oriented (and applied) research		4 3						
	3. To support knowledge flow between scientific disciplines		4 2						
	4. To assure availability of human resources	4							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 2		n.d.			O4. Patents **112** O5.Companies **217**
	6. The adoption of biotechnology for new industrial applications						n.d.	0	
	7. To assist firm creation	0			3 2	n.d.	n.d.		
Market	8. To monitor and improve the social acceptance of biotechnology							1	O6. Accept. Index[23] **100,18** O7. Drug approvals **0** O8. Field Trials **122** O9. Production **141**
	9. To facilitate the introduction of new products					n.d.			
	10. To strengthen the economic sectors exploiting biotechnology						n.d.		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						n.d.		
Industry	12. To encourage business investment in R&D						n.d.		O10. IPOs **42** O11. Pub. Comp. **40** O12. VC in Biotech **104** O13. Venture Cap **103**
	13. To improve firm's competitiveness	0				n.d.	n.d.		
	14. To exploit regional potentials				1				

23 EU Average is 100,29. See annex 5.

Finland 2004

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 / 5			4		
	2. To promote high level of industry-oriented (and applied) research		5 / 5					
	3. To support knowledge flow between scientific disciplines		5 / 5					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 / 0		5		
	6. The adoption of biotechnology for new industrial applications						0	1
	7. To assist firm creation	2			3 / 0	0	0	
Market	8. To monitor and improve the social acceptance of biotechnology							3
	9. To facilitate the introduction of new products					0		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				3		0	
	13. To improve firm's competitiveness	2				3	0	
	14. To exploit regional potentials				n.d.			

7 France

Policy profile of 1994/95

The French policy profile for the period 1994/95 indicates about average policy engagement in most policy areas in the middle of the 1990s. Focus of this commitment was education policy aiming at ensuring the availability of human resources for life sciences and technology transfer mechanisms where a high level of policy activity could be observed. On the other side, the introduction of new products and the exploitation of regional potentials presented quite low policy engagement. Concerning the market and industrial development, policy activities were concentred on fiscal measures to support the various policy goals. According to the available information these policies mainly followed generic approaches to support the biotechnology knowledge base.

Output indicators of the knowledge base were about the level of European average (exception of human resources indicator O3 which is well below the European average). Indicators of knowledge transmission were well below the average index. On the demand side, the indicators were above, or well above (see indicator O8 for field trials) the European average. Indicators of industrial development were slightly below the European average (indicator O13, which captures the venture capital investment per capita) was above the average index but indicator O12 (which captures the venture capital investment in biotechnology) was below the European average.

Concerning the relation between policy goals, policy areas and output indicators, which provide information on the achievement of policy goals, the following conclusions can be drawn:

- From a general view point, it seems that the average policy commitment in supporting the first three policy goals (knowledge base and human resources, knowledge transmission, market) brought about average output indicators in these areas. We can also observe, on the market side, that a rather good performance seemed not to be driven by intensive policy activities in the respective areas.
- More specifically, the rather intensive policy activities in supporting availability of human resources did not contribute well to the achievement of the policy goal (at least at the level of programmes to provide human resources with skills for advanced research). We also observe very high generic activities to facilitate transmission of knowledge from academia to industry in the 1994/95 period and only well below average output indicators. This raises the question whether the generic approach in this area might not be appropriate to achieve the policy goal, so that rather more specific approaches would be more suitable.

Policy profile of 2004

In 2004, the biotechnology was a high priority for the government. France dedicated more than 5 % of the national public R&D budget in biotechnology. Pharmaceutical, bio-processing and agro-food industries had the favour of public priorities. In recent years policy has focused on the commercialisation of biotechnology, with different measures to support firm creation, innovation in Small and Medium Enterprises (SMEs) and large firms as well as on designing a favourable environment for biotechnology, including public acceptance consultation. Instruments designed during the late 1990's to support firm creation and technology transfer mechanisms have been reinforced and are well established in the institutional landscape.

In France policy-makers, universities and industrial organisations are committed to the assessment of the impact of biotechnology policies. This concerns economic, environmental and ethical aspects, the formation of geographic (regional) clusters and public acceptance (new law). The ministry of economic affairs plays an increasing role in stimulating biotechnology. Regarding the implementation of European directives, the patentability of biotechnology inventions and the marketing and release of genetically modified organisms are still controversial.

Dynamic changes in the policy profiles

The 2004 French policy profile indicates that France has reinforced its priorities towards biotechnology in comparison with the period 1994/95. One of the weaknesses which was already pointed out in the EPOHITE report is being addressed by the government: coordination of research initiatives amongst public sector research organisations. Coordination has been reinforced through the creation of agencies and a new law for research organisation, which is being discussed.

France 1994/95

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators: 2002 *or latest available year* 100 = EU Average
Knowledge base and human resources	1. To promote high level of biotechnology basic research		3 0			3			O1. Publications **103** O2. Citations **111** O3. Graduates **29**
	2. To promote high level of industry-oriented (and applied) research		3 0						
	3. To support knowledge flow between scientific disciplines		2 0						
	4. To assure availability of human resources	5							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			5 0		3			O4. Patents **83** O5.Companies **60**
	6. The adoption of biotechnology for new industrial applications						3	0	
	7. To assist firm creation	0			2 0	4	2		
Market	8. To monitor and improve the social acceptance of biotechnology							2	O6. Accept. Index[24] **101,12** O7. Drug approvals **98** O8. Field Trials **193** O9. Production **120**
	9. To facilitate the introduction of new products					0			
	10. To strengthen the economic sectors exploiting biotechnology						3		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						3		
Industry	12. To encourage business investment in R&D				0		3		O10. IPOs **93** O11. Pub. Comp. **76** O12. VC in Biotech **93** O13. Venture Cap **142**
	13. To improve firm's competitiveness	0				1	3		
	14. To exploit regional potentials				1				

24 EU Average is 100,29. See annex 5.

France 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 5			3		
	2. To promote high level of industry-oriented (and applied) research		5 4					
	3. To support knowledge flow between scientific disciplines		2 0					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 1		4		
	6. The adoption of biotechnology for new industrial applications						3	3
	7. To assist firm creation	5			4 1	5	4	
Market	8. To monitor and improve the social acceptance of biotechnology							4
	9. To facilitate the introduction of new products					5		
	10. To strengthen the economic sectors exploiting biotechnology						3	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						3	
Industry	12. To encourage business investment in R&D				4		4	
	13. To improve firm's competitiveness	5				4	4	
	14. To exploit regional potentials				n.d.			

8 Germany

Policy profile of 1994/95

The German policy profile of the mid 1990s indicates a rather broad approach towards supporting biotechnology. In most areas policy instruments have been implemented. Nevertheless in the policy portfolio, policies aiming at promoting biotechnology basic and applied research have been the most intensive in the middle of the 1990s. The rather broad policy approach implies that for most policy goals at least some policy activities have been implemented. However, the support of knowledge flow between scientific disciplines, the assurance of the availability of human resources and market-oriented policy goals seem to have got less support by the various policy areas. A particular high level of policy activity aims at exploiting regional potentials in biotechnology.

On the output side, in the year 2002 the publication indicator is a little below the average while on the other hand the quality of the publications indicated by the citation indicator is above average. The human resource indicator O3 is well below the European average. With respect to knowledge transmission Germany outperforms the European average in terms of patent applications while the number of companies related to the size of the country is below the average. Most market indicators reveal rather moderate performance. Interestingly the acceptance index is clearly above the European average for "West Germany" (and slightly above the average for "East Germany") (see footnote on previous page). With respect to industrial development there has been a high level of venture capital investment in biotechnology. On the other hand related to the size of the country (number of inhabitants) venture capital investment is well below average.

Concerning the relation between policy goals, policy areas and output indicators the following observations can be made:

- It is not clear whether the mainly generic activities in research policy to promote a high level of biotechnology basic research have been the best suited approach to achieve this goal. Publication and citation figures reveal a mixed performance picture. The promotion of industry-oriented and applied research seems to have been successful as indicated by the high patent indicator.
- There seems to be a problem in education policies where a rather low level of policy activity in the middle of the 1990s corresponds to a rather low output.
- Concerning knowledge transmission there has been a number of activities to assist firm creation, however, if the number of companies is related to the size of the country the respective output indicator reveals below average performance. In

addition the exploitation of regional potentials which had been a very high priority on the political agenda also aimed mainly at firm creation. The comparison between the output and policy activity leads to the question whether the adopted policy approaches have been best suited to achieve the goal of assisting firm creation.

Policy profile of 2004

In 2004 Germany dedicated between 2 and 4 % of the national public R&D budget to biotechnology. According to the information available, policy efforts tackled policy goals relevant for the knowledge base, knowledge transmission and for industry. In general terms, the knowledge base is the most promoted area of the innovation system. The market for biotechnology products seems to be the neglected area of the German biotechnology innovation system in 2004 in terms of policy attention.

Regarding the different policy areas active in promoting biotechnology, in 2004 research policy (with an equilibrated combination of generic and biotechnology-specific instruments) has focused on supporting basic and applied research. The intensity of research policy is very high compared with the other policy areas. However, research policy seems to be neglecting the promotion of knowledge flow between scientific disciplines.

Another strong policy area is policy fostering industrial development. With a quite lower level of policy engagement than research policy, industrial policy targets especially firm creation and the exploitation of regional developments. Germany is the Member State with the strongest focus on cluster initiatives to promote innovation. On the other side, the policy engagement on exploitation (with specific instruments to promote the transmission of knowledge between the relevant actors, especially between industry and academia) is quite low.

Other policy gaps appear in the areas of education, regulation, fiscal policy and demand. Especially two policy gaps are worrying: the low support for the education qualified human capital (with the necessary combination of skills in biotechnology and business) and the disregard of the need to create a suitable regulatory framework for innovation considering research, market and industrial issues. Only the issues of patenting biotechnology inventions and the special intellectual property regime for public research organizations have been tackled.

Furthermore, according to the available information, Germany does not implement any kind of fiscal measures to create incentives in the innovation system. The adoption of biotechnology by companies in established industries is not an issue in the German policy profile of 2004.

Regarding the processes of implementing and assessing policy, Germany conducts impact assessments after the policy initiatives have been implemented. Institutional mechanisms to guarantee policy coordination among regions or ministries do not exist. Regarding the process of implementing EC directives relevant for the regulatory framework of biotechnology innovation system, the process in Germany seems to be very slow and controversial in all selected directives. The directive 2001/18/EC (Marketing and release of GMOs) is still in the process of being implemented into national law.

Dynamic changes in the policy profile

As in the period 1994/95, the German policy profile in 2004 has maintained a focus on promoting the biotechnology knowledge base. The implementation of biotechnology-specific initiatives has been intensified. In the same line, industrial development policy continue to be the second largest stake in the German policy profile with an emphasis on supporting the exploitation of regional potentials through cluster building. Also in this policy area the implementation of biotechnology-specific instruments to support firm creation has been intensified. The trend suggests a concentration of the policy efforts in the knowledge base and industry issues while market issues and mechanisms for knowledge transmission seem to be loosing relevance for the policy system. The engagement of policy areas targeting these two aspects (the policy areas of regulation, demand and exploitation) has been weaker in the policy profile of 2004. Furthermore, the area of education policy has not covered the gaps already observed in 1994/95.

The trend in the German policy profile shows a concentration of the policy efforts towards the development of the knowledge base and towards industry through specific measures to target selected goals in these areas of the innovation system. However, support measures for other features of the innovation system such as the regulatory framework conditions for research and innovation and the demand are disappearing from the policy agenda. This trend might slow down the innovation process.

Germany 1994/95

	Policy goals	Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators: 2002 *or latest available year* 100 = EU Average
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 3			2			O1. Publications **89** O2. Citations **126** O3. Graduates **52**
	2. To promote high level of industry-oriented (and applied) research		3 4						
	3. To support knowledge flow between scientific disciplines		1 1						
	4. To assure availability of human resources	2							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			2 3		2			O4. Patents **124** O5.Companies **65**
	6. The adoption of biotechnology for new industrial applications						0	3	
	7. To assist firm creation	0			3 3	2	0		
Market	8. To monitor and improve the social acceptance of biotechnology							3	O6. Accept. Index[25] **OFS: 101,70** **NFS: 100,41** O7. Drug approvals **49** O8. Field Trials **36** O9. Production **84**
	9. To facilitate the introduction of new products					2			
	10. To strengthen the economic sectors exploiting biotechnology						0		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0		
Industry	12. To encourage business investment in R&D				3		0		O10. IPOs **158** O11. Pub. Comp. **109** O12. VC in Biotech **190** O13. Venture Cap **61**
	13. To improve firm's competitiveness	0				1	0		
	14. To exploit regional potentials				5				

25 EU Average is 100,29. See annex 5. In the case of Germany a combined index for the whole country was not feasible. OFS stands for "Old federal states or West Germany". NFS stands for "New federal states or East Germany".

Germany 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 / 4			0		
	2. To promote high level of industry-oriented (and applied) research		4 / 5					
	3. To support knowledge flow between scientific disciplines		1 / 1					
	4. To assure availability of human resources	2						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			2 / 2		4		
	6. The adoption of biotechnology for new industrial applications						0	0
	7. To assist firm creation	0			4 / 3	0	0	
Market	8. To monitor and improve the social acceptance of biotechnology							3
	9. To facilitate the introduction of new products					0		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				3		0	
	13. To improve firm's competitiveness	0				1	0	
	14. To exploit regional potentials				5			

9 Hungary

Policy profile of 2004

In 2004, Hungary dedicated 1-2 % of its national R&D budget to biotechnology. Pharmaceuticals and agro-food are the two main sectors benefiting from biotechnology. Although benefiting from the development of biotechnology, chemicals and laboratory equipment and supplies are less central in Hungary.

Biotechnology in Hungary already combines several policy areas and goals. Although the policy profile of Hungary leaves room for the intensification of policy priorities in the future, the striking feature is that none of the policy areas or goals is being ignored. Biotechnology background education (human resources) remains a secondary target whereas firm improvement and competitiveness are being ignored. The most important policy areas are research, regulation and fiscal measures. Policies for education and demand are the least used.

In terms of policy goals, sustaining the knowledge base and human resources by means of both generic and specific policies is given moderate emphasis. As far as knowledge transmission is concerned, there is a general preference for generic instruments rather than policies dedicated to biotechnology. The main instrument for industrial development is to assist firm creation. Market and industry are also moderate policy goals.

In Hungary, there is no assessment of the impact of biotechnology policies. Responses to the questionnaire indicate that there is no formal mechanism for coordinating biotechnology policies. European directives related to patentability of biotechnology and to the use of GMOs have been adopted at reasonable speed and with no noticeable controversy.

Hungary 2004

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		2 2			2		
	2. To promote high level of industry-oriented (and applied) research		2 2					
	3. To support knowledge flow between scientific disciplines		3 3					
	4. To assure availability of human resources	2						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			3 1		2		
	6. The adoption of biotechnology for new industrial applications						3	0
	7. To assist firm creation	0			4 0	3	2	
Market	8. To monitor and improve the social acceptance of biotechnology							1
	9. To facilitate the introduction of new products					3		
	10. To strengthen the economic sectors exploiting biotechnology						3	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						3	
Industry	12. To encourage business investment in R&D				3		3	
	13. To improve firm's competitiveness	0				2	3	
	14. To exploit regional potentials				n.d.			

10 Ireland

Policy profile of 1994/95

The Irish policy portfolio in the middle of the 1990s indicated that most policy activities concentrated on the first two biotechnology areas: knowledge base/human resources and knowledge transmission. With respect to the market and industrial development, only low policy activities could be observed. Strong efforts by education policies aimed to ensure the availability of human resources. The promotion of high-level industry-oriented and applied research was also supported by intensive R&D policy efforts. With respect to basic research policy, activities were about moderate.

On the output side, Ireland performed slightly below the average in terms of publications, citations and patents. A better performance can be observed for the human resource indicator. The number of companies per capita in Ireland is above the European average. On the other hand, available market and industrial development indicators exhibit well below average performance.

The following observations can be made with respect to the interrelation between policy goals, policy areas and output indicators:

- There seems to be a good match between rather intensive education policy activities supporting the availability of human resources and the number of graduates.
- The same holds true for research policy activities supporting the promotion of basic research where average policy intensity goes along with slightly below average performance.
- Also with respect to policy goal 5 - transmission of knowledge from academia to industry - policy intensity and output in terms of patent applications seem to point to a link between these two variables.

An interesting case can be observed for the policy goal to assist firm creation where we find a rather low level of policy activities on the one hand and a level of output above the European average on the other hand. There does not seem to be a close relationship between these policy activities in the middle of the 1990s and the number of firms in 2002. The high number of firms may have some connection to strong policies to promote a high level of industry-oriented research.

Policy profile of 2004

In 2004, Ireland dedicated more than 5 % of its national R&D budget to biotechnology. There are many sectors engaged in the development of biotechnology:

pharmaceuticals, chemicals, agro-food, laboratory equipment and supplies. Ireland has both diversified its policy areas and policy goals. In terms of areas, all aspects are being exploited to a considerable extent. An important emphasis is now on fiscal measures, which have crucial importance in 2004. Research and education are the second most important policy areas. Exploitation, industrial development, regulation and demand are the least - but still very important policy areas. Transmission of knowledge through firm creation and industrial applications are encouraged through a variety of mechanisms. These are in line with the incentives to attract large firms. Markets and business investment in R&D and competitiveness are also important policy goals. Exploitation of regional potential is not completely dismissed; given the small size of the country, this is not a major issue.

In Ireland, policy-makers, universities and industrial organisations are committed to the assessment of the economic impact of biotechnology policies during and after the programme. This is accompanied by formal mechanisms to coordinate biotechnology policies, both in a geographic sense (e. g. national coordination of regional policies) and in terms of objectives (education, science, industry, etc.). This coordination is organised at all levels (ministries, inter-ministerial cabinet, and independent board). All European directives related to biotechnology (patentability of biotechnology inventions, use of GMOs, commercialisation of GMOs) have been adopted at high speed.[26] Unlike other EC directives, the commercialisation of GMOs has provoked (unresolved) controversy arising mainly from the final users.

Dynamic changes in the policy profile

There has been significant change in the Irish policy profile over the last decade. In particular, the policy profile has broadened considerably and areas neglected in 1994 (strengthening industry and the market) are now addressed by policy. Highest priority for achieving these goals is given to fiscal instruments, but the inclusion of compulsory business administration and innovation courses in Masters degrees in biotechnology aims both to support company competitiveness and assist industrial development. Other important dynamic changes are the increased priority given to the funding of basic research and a stronger focus on various methods to promote knowledge transmission, including fiscal measures.

It is anticipated that strengthening all areas of the Irish policy profile for biotechnology will improve performance in those areas where Ireland has so far been relatively weak:

26 Data is missing on implementation of EC Directives for the protection of the work-force

knowledge transmission, the strength of the market and performance in industrial activities.

Ireland 1994/95

	Policy goals	Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators: 2002 *or latest available year* 100 = EU Average
Knowledge base and human resources	1. To promote high level of biotechnology basic research		2 3			n.d.			O1. Publications **80** O2. Citations **83** O3. Graduates **301**
	2. To promote high level of industry-oriented (and applied) research		0 5						
	3. To support knowledge flow between scientific disciplines		1 0						
	4. To assure availability of human resources	4							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			2 2		n.d.			O4. Patents **74** O5.Companies **133**
	6. The adoption of biotechnology for new industrial applications						0	2	
	7. To assist firm creation	0			1 2	n.d.	2		
Market	8. To monitor and improve the social acceptance of biotechnology							0	O6. Accept. Index[27] **100,28** O7. Drug approvals **0** O8. Field Trials **30** O9. Production **n.a.**
	9. To facilitate the introduction of new products					n.d.			
	10. To strengthen the economic sectors exploiting biotechnology						0		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0		
Industry	12. To encourage business investment in R&D				1		0		O10. IPOs **91** O11. Pub. Comp. **173** O12. VC in Biotech **30** O13. Venture Cap **66**
	13. To improve firm's competitiveness	0				n.d.	0		
	14. To exploit regional potentials				0				

27 EU Average is 100,29. See annex 5.

Ireland 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		4 5			3		
	2. To promote high level of industry-oriented (and applied) research		3 3					
	3. To support knowledge flow between scientific disciplines		4 5					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			5 2		3		
	6. The adoption of biotechnology for new industrial applications						5	3
	7. To assist firm creation	3			4 2	3	4	
Market	8. To monitor and improve the social acceptance of biotechnology							2
	9. To facilitate the introduction of new products					3		
	10. To strengthen the economic sectors exploiting biotechnology						5	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						5	
Industry	12. To encourage business investment in R&D				3		5	
	13. To improve firm's competitiveness	3				3	5	
	14. To exploit regional potentials				0			

11 Italy

Policy profile of 1994/95

The Italian policy profile for the period 1994/95 shows that there had not been many biotechnology-specific activities in research and exploitation policy in the middle of the 1990s. However, there had been rather intensive education policy activities to assure the availability of human resources for biotechnology. According to the available information most other policy activities had been less intense or absent.

Output indicators point to a rather weak performance of Italy in most categories. The only exceptions are field trials and the industry indicators O10 (number of IPOs in biotechnology in the stock market per number of biotechnology companies) and O13 (number of biotechnology companies in the stock market per number of biotechnology companies) where Italy performed above the European average. The production figure indicates that, in principle, the size of the Italian industry is attractive for biotechnology.

Concerning the relation between policy goals, policy areas and output indicators, two observations can be put forward:

- There are mainly generic activities of policies related to knowledge base and human resources. In addition there is a certain mismatch between rather high activities aiming at assuring the availability of human resources and the low output of the system in terms of life sciences graduates.
- On the industry side, we observe that a rather high performance (indicators O10 and 013) seems not to be driven by intensive policy activities in the respective areas.

Policy profile of 2004

In 2004, Italy dedicated between 1 and 2 % of the national public R&D budget to biotechnology. The 2004 Italian policy profile shows that the availability of qualified human capital and, to a lesser extent, basic and industry-oriented research are the most important policy targets. Priorities have not been given to commercialisation of biotechnology or firm creation. Public authorities put the accent on pharmaceutical industry, and to a lesser extent, on the chemical industry. Public policies put little specific emphasis on the creation of a favourable environment for biotechnology.

Specific mechanisms to assess the impacts of policy measures related to biotechnology have been implemented in Italy. Policy-makers, universities and research institutions are involved in the process of elaborating each new policy initiative. Social and environmental impacts and ethical aspects are generally considered. The establishment of governmental commissions, made by experts on the field, guarantees the coordination between regional and national policy instruments and activities. Co-ordination among independent ministries occurs through an inter-ministerial institution where representatives from different ministries are involved. Most of the EC directives have not been implemented yet and, if they have been implemented the process has been controversial (the contained use of genetically modified micro-organisms 98/81/EC, and marketing and release of genetically modified organisms 2001/18/EC).

Dynamic changes in the policy profile

The situation of 2004 is not really different from 1994/95 in terms of policy priorities. In both periods the availability of qualified human capital and, to a lesser extent, basic and industry-oriented research have been the most important policy targets.

As biotechnology seems not to have been a priority, output indicators in 2002 were rather weak for Italy in almost all categories except for field trials. However, the scientific environment has to be stimulated for developing and keeping qualified manpower (to avoid brain drain).

Italy 1994/95

	Policy goals	Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators: 2002 *or latest available year* 100 = EU Average
		Policy Area							**Output Indicators**
Knowledge base and human resources	1. To promote high level of biotechnology basic research		3 0			3			O1. Publications **52** O2. Citations **90** O3. Graduates **77**
	2. To promote high level of industry-oriented (and applied) research		2 0						
	3. To support knowledge flow between scientific disciplines		2 0						
	4. To assure availability of human resources	5							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			5 0		1			O4. Patents **25** O5.Companies **13**
	6. The adoption of biotechnology for new industrial applications						2	0	
	7. To assist firm creation	0			2 0	2	2		
Market	8. To monitor and improve the social acceptance of biotechnology							n.d.	O6. Accept. Index[28] **100,58** O7. Drug approvals **0** O8. Field Trials **122** O9. Production **101**
	9. To facilitate the introduction of new products					2			
	10. To strengthen the economic sectors exploiting biotechnology						2		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						2		
Industry	12. To encourage business investment in R&D				0		2		O10. IPOs **249** O11. Pub. Comp. **178** O12. VC in Biotech **8** O13. Venture Cap **89**
	13. To improve firm's competitiveness	0				2	2		
	14. To exploit regional potentials				0				

28 EU Average is 100,29. See annex 5.

Italy 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		4 / 2			4		
	2. To promote high level of industry-oriented (and applied) research		5 / 2					
	3. To support knowledge flow between scientific disciplines		2 / 1					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			2 / 1		2		
	6. The adoption of biotechnology for new industrial applications						0	0
	7. To assist firm creation	2			1 / 0	2	0	
Market	8. To monitor and improve the social acceptance of biotechnology							2
	9. To facilitate the introduction of new products					2		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				1		2	
	13. To improve firm's competitiveness	2				1	2	
	14. To exploit regional potentials				1			

12 Lithuania

Policy profile of 2004

The Lithuania policy profile is broadly characterised by a relatively high level of policy instruments at the upper half of the policy matrix that address the policy goals knowledge generation, knowledge transmission and human resource. No policy instruments exist that address policy goals in the categories markets and industry.

Education policies is highly relevant. Public policies exist that support educational institutions to support programmes/curricula in biotechnology on all levels: undergraduate, masters and doctoral. Generic and biotech policy instruments for basic research, applied research and for supporting international mobility are running in Lithuania. Biotech-specific policies are considered as very important in this set of instruments. Public investments in biotechnology are below 0.1 % of the public R&D budget.

Commercial exploitation is mainly promoted through creation of S&T parks and incubator facilities. Collaborative research is promoted through grants for industrial research involving collaboration with public researchers, through exchange programmes between academia and industry and through innovation centres. In the category of policies for industrial development, direct subsidies and a set of support measures (infrastructure facilities, consulting and advisory services in management and regulatory issues) for starting high-tech companies are available. All of these are generic policy instruments. Lithuania does not have a specific biotech industry development policy.

There are no fiscal policies to promote innovation or regulatory frameworks to promote innovation. Similarly, demand-oriented policies, policy coordination and policy impact assessment have not been established. Finally, most of the relevant EC directives on biotechnology have been implemented (with the exception of the patentability of biotechnology inventions).

Lithuania 2004

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		2 / 4			0		
	2. To promote high level of industry-oriented (and applied) research		2 / 4					
	3. To support knowledge flow between scientific disciplines		2 / 4					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			2 / 0		0		
	6. The adoption of biotechnology for new industrial applications						0	n.d.
	7. To assist firm creation	0			2 / 0	0	0	
Market	8. To monitor and improve the social acceptance of biotechnology							n.d.
	9. To facilitate the introduction of new products					0		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				0		0	
	13. To improve firm's competitiveness	0				0	0	
	14. To exploit regional potentials				n.d.			

13 Luxembourg

Policy profile of 1994/1995

For the policy profile of Luxembourg of 1994/1995 only scarce information is available on the policy activities. This information shows that only generic research policy approaches aiming at supporting the promotion of technology in basic and applied research exist. In addition, there were some generic policy activities aiming at facilitating the transmission of knowledge from academia to industry. To encourage business investment in R&D, also a few generic policy instruments, such as research grants and loans for companies carrying out R&D, were installed.

On the output side, the data that are available indicate that in terms of publications, patent applications and acceptance, Luxembourg is performing below the European average.

Policy profile of 2004

The overall policy profile of 2004 of Luxembourg is rather similar to the 1994-1995 profile. Research policies exist, but information about the type of instruments and the relative importance of these instruments is not available. The share of the national public R&D budget flowing into biotechnology is estimated as very low, if not nil. There are no statistics available that could indicate the domains into which public R&D funds for biotechnology are flowing into.

In 2004 no biotechnology specific, only generic policy instruments existed. Examples are generic policy instruments to stimulate collaboration between public and private research and to encourage R&D activities in established companies. These instruments mainly include research grants and loans for companies carrying out R&D.

Also several instruments for supporting the commercial exploitation of research and stimulating high technology start-ups existed in 2004. There are grants for scientists to write a business plan and several activities for providing financial support and improving the availability of financial capital for high tech start-ups, including loans, tax benefits and public equity investment. In addition, Luxembourg has generic policy approaches to promote the establishment of facilities and to offer companies consulting and advisory services in management issues.

Concerning the creation of attractive framework conditions, Luxembourg takes into account the regulatory framework conditions for company creation and growth, when designing regulations. These regulations are, however, not specifically adapted to specific conditions and requirements of various sectors and industries. EC directives concerning the contained use, marketing and release of GMO are implemented, but very slowly, because these directives are considered as rather controversial. Because of the high controversy, the directive regarding the patentability of biotechnology inventions has not been implemented yet.

On the demand side, in 2004 Luxembourg has public policies supporting initiatives to explore benefits, costs and risks of the application of biotechnology. The national public research fund uses multi-annual plans in order to orient the research projects financed. Issues concerning ethics, regulation, developing countries and future developments are considered, mainly by policy-makers and representatives of universities and research institutions. Other stakeholders, such as companies, citizens and NGOs are not involved in these initiatives. Luxembourg has not implemented instruments to inform non-expert citizens about biotechnology, nor are there policies that stimulate the adoption for new industrial applications by companies that are not performing biotech R&D themselves.

Regarding the policy process, Luxembourg has not implemented activities to assess the impact of policy measures, nor exist formal mechanisms to coordinate policy instruments promoting biotechnology available.

Dynamic changes in the policy profile

The overall policy profile for Luxembourg has not changed drastically since 1994/1995. The same type of generic instruments exists and there are no biotechnology-specific approaches implemented. The share of the national public R&D budget in biotechnology research is still very low, if not nil.

What has increased since 1994/1995 is the support for the creation and growth of high technology start-ups. Luxembourg had in 2004 several generic policy instruments to support spin-offs from universities and high technology start-ups. There are several initiatives to improve the availability of financial capital as well as instruments to promote facilities and other forms of business support for start-ups. This increase in the support for high technology start-ups may contribute to better conditions for scientists that want to start a company and for young biotechnology companies. This could result in more newly established biotechnology firms as well as in a higher level of investments in these companies.

Luxembourg 1994/1995

	Policy goals	Policy Area							Output Indicators
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Index 100 = EU Average
Knowledge base and human resources	1. To promote high level of biotechnology basic research		3 0			n.d.			O1. Publications **28** O2. Citations **54** O3. Graduates **0**
	2. To promote high level of industry-oriented (and applied) research		3 0						
	3. To support knowledge flow between scientific disciplines		0 0						
	4. To assure availability of human resources	n.d.							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			1 0		n.d.			O4. Patents **29** O5.Companies **n.a.**
	6. The adoption of biotechnology for new industrial applications						n.d.	n.d.	
	7. To assist firm creation	n.d.			0 0	n.d.	n.d.		
Market	8. To monitor and improve the social acceptance of biotechnology							n.d.	O6. Accept. Index[29] **101,58** O7. Drug approvals **0** O8. Field Trials **n.a.** O9. Production **n.a.**
	9. To facilitate the introduction of new products					n.d.			
	10. To strengthen the economic sectors exploiting biotechnology						n.d.		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						n.d.		
Industry	12. To encourage business investment in R&D				0		n.d.		O10. IPOs **0** O11. Pub. Comp. **0** O12. VC in Biotech **n.a.** O13. Venture Cap **n.a.**
	13. To improve firm's competitiveness	n.d.				n.d.	n.d.		
	14. To exploit regional potentials				n.d.				

29 EU Average is 100,29. See annex 5.

Luxembourg 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		0 0			0		
	2. To promote high level of industry-oriented (and applied) research		0 0					
	3. To support knowledge flow between scientific disciplines		0 0					
	4. To assure availability of human resources	0						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			1 0		0		
	6. The adoption of biotechnology for new industrial applications						0	1
	7. To assist firm creation	0			3 0	2	0	
Market	8. To monitor and improve the social acceptance of biotechnology							1
	9. To facilitate the introduction of new products					3		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				0		0	
	13. To improve firm's competitiveness	0				1	0	
	14. To exploit regional potentials				0			

14 The Netherlands

Policy profile of 1994/95

The Netherlands presented in the period 1994/95 a broad policy profile where all policy goals are addressed in one way or another. However, policy efforts seem to focus more on the early stages of the innovation process disregarding market and industrial development. All policy areas, from education up to demand policy are more or less active in promoting biotechnology in this period. Education and research policy (especially with generic instruments) as well as generic fiscal measures seem to be active policy areas. Regulation focuses mostly on issues related to basic research. In the demand side policy mainly focuses on the public acceptance of biotechnology. Finally, policy measures for the industrial application of research results and industrial development are relatively weak in this period.

The promotion of basic and applied research is quite balanced, although applied research seems to be more promoted, especially through biotechnology-specific instruments. The mobility of scientists presents a gap in research policy. Additionally, policy goals dealing with knowledge transmission and the industrial application of biotechnology are pursued with a balanced but very weak combination of the relevant policy areas. The support of firm creation is low. Additionally, the market processes (demand and supply development and interaction) are supported with demand policy and generic fiscal measures to incentive private investment. However, in regulatory issues relevant for market processes there seems to be an important policy gap.

The performance of the Dutch knowledge base (based on publications and citations) is above the European average. The number of graduates in life science per capita is very low. The Dutch knowledge base transmission indicators outperform the European average in the number of biotechnology patents applications per capita. The firm creation performance is below the European average. Both, the number of bio-medicines per capita and the number of field trails are well below the European average. The indicators for the demand side (biotechnology acceptance and production in relevant economic sectors) are above average. In contrary to the market indicators, the industry indicators outperform the European average. The Dutch performance especially concerning the numbers of IPO's, venture capital available and venture capital invested in biotechnology is very high.

Policy profile of 2004

The policy profile of the Netherlands is also in 2004 rather broad: all policy areas are involved in the promotion of biotechnology. Most policy goals and most policy areas receive attention. More than 5 % of the national R&D budget is spend on biotechnology. A broad range of sectors is addressed in biotechnology policies in the Netherlands: pharmaceuticals, agro food, chemicals, laboratory equipment and supplies and specific fields like tissue engineering.

In the Netherlands, the impact of biotech policy is assessed in the process of elaborating a new policy initiative and after the policy initiative has been implemented. Several stakeholders are involved in the assessments: policy-makers directly involved in the elaboration of the policy initiative, representatives from industry and their business organisations, form social groups and non-expert citizens. Economic and social (such as job creation, education careers) impacts for the short term (0–5 years) are addressed in the assessments. Also the geographical dimensions is relevant as attracting foreign companies to the Netherlands is one of the issues.

Formal mechanisms for the coordination of biotechnology policy do not exist: informal do (interdepartmental group biotechnology). All EC directives have been implemented; some of them fast and without any controversy (contained use, protection of workers), some are rather controversial like the ones on patents, GM organism, GM foods and labelling.

Dynamic changes in the policy profile

There are some interesting differences between the policy profiles of 1994/95 and 2004. First of all, in 2004 the number and size of dedicated biotechnology research programmes is considerable higher, compared to the previous period. Second, a broad set of biotech transmission instruments has been running in the period 2000–2004 that supported firm creation. It included a start-ups venture fund, infrastructure facilities, consulting and advisory services in management issues and IPR issues.

A third important development that characterises the 2004 profile and differs considerable from the 1994/95 profile concerns the policies to exploit the regional potentials. In 2004 regional innovation policy-making has gained importance. The (network of) biotechnology incubators play an important role in this respect. In six Dutch university towns biotechnology incubators have been set up. They function as catalysts in economic development processes in the regions.

Regulation was and is a high priority issue in biotechnology policy (nowadays de-regulation is a topic). The same accounts for fiscal policies. They kept their high scores.

The Netherlands 1994/95

	Policy goals	Policy Area							Output Indicators
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	**2002** ***or latest available year*** **100 = EU Average**
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 / 2			5			O1. Publications **148** O2. Citations **127** O3. Graduates **34**
	2. To promote high level of industry-oriented (and applied) research		5 / 4						
	3. To support knowledge flow between scientific disciplines		0 / 0						
	4. To assure availability of human resources	4							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			3 / 2		1			O4. Patents **154** O5.Companies **78**
	6. The adoption of biotechnology for new industrial applications						5	0	
	7. To assist firm creation	0			2 / 1	1	3		
Market	8. To monitor and improve the social acceptance of biotechnology							4	O6. Accept. Index[30] **101,29** O7. Drug approvals **0** O8. Field Trials **77** O9. Production **117**
	9. To facilitate the introduction of new products					1			
	10. To strengthen the economic sectors exploiting biotechnology						5		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						5		
Industry	12. To encourage business investment in R&D				1		5		O10. IPOs **149** O11. Pub. Comp. **107** O12. VC in Biotech **155** O13. Venture Cap **183**
	13. To improve firm's competitiveness	0				1	5		
	14. To exploit regional potentials				0				

30 EU Average is 100,29. See annex 5.

The Netherlands 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		4 / 4			5		
	2. To promote high level of industry-oriented (and applied) research		3 / 5					
	3. To support knowledge flow between scientific disciplines		4 / 0					
	4. To assure availability of human resources	3						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 / 3		4		
	6. The adoption of biotechnology for new industrial applications						5	0
	7. To assist firm creation	1			2 / 2	4	3	
Market	8. To monitor and improve the social acceptance of biotechnology							4
	9. To facilitate the introduction of new products					4		
	10. To strengthen the economic sectors exploiting biotechnology						5	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						5	
Industry	12. To encourage business investment in R&D				0		5	
	13. To improve firm's competitiveness	1				4	5	
	14. To exploit regional potentials				2			

15 Poland

Policy profile of 2004

In 2004, Poland dedicated less than 1 % of its national R&D budget to biotechnology. Biotechnology is not associated with any clear leading sector. Rather, all sectors generally thought to have potential for the application of biotechnology (pharmaceuticals, chemicals, agro-food and laboratory equipment and supplies) are considered to be important adopters of biotechnology development.

Biotechnology is a completely new policy priority in Poland. As the policy profile shows, few of the policy areas are targeted, with the exception of education. Education receives moderate attention from policy-makers. Interestingly, education policy is linked with human resources, knowledge transmission and the improvement of firm competitiveness. This shows that policy-makers are aware of the pervasive character of biotechnology, spreading from basic to more applied issues. There are great concerns regarding the lack of emphasis on research, which, as an input, cannot be disregarded.

The case of Poland raises interesting questions regarding the coherence of policies. Arguably, there is little to be gained in promoting education for knowledge transmission, markets and industry in the absence of additional, complementary policies regarding the other policy goals and tools. The absence of fiscal incentives can prove prohibitive, whereas the lack of concern for industrial application and development is likely to prove a barrier to entrepreneurship and commercial exploitation.

In Poland, there is no assessment of the impact of biotechnology policies. Responses on the questionnaire indicate that there is no formal mechanism for the coordination of biotechnology policies. However, as has been stressed by the respondent, policies are currently being framed in a more integrated manner. Thus, the policy profile presented here is likely to underestimate new policies areas and goals that it is anticipated will be introduced in the near future. All European directives (patentability of biotechnology inventions, use of GMOs, commercialisation of GMOs, protection of workforce) have now been adopted at varying speeds.

Poland 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		1 0			0		
	2. To promote high level of industry-oriented (and applied) research		1 0					
	3. To support knowledge flow between scientific disciplines		0 0					
	4. To assure availability of human resources	3						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			1 0		2		
	6. The adoption of biotechnology for new industrial applications						0	0
	7. To assist firm creation	3			0 0	0	0	
Market	8. To monitor and improve the social acceptance of biotechnology							2
	9. To facilitate the introduction of new products					0		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				0		0	
	13. To improve firm's competitiveness	3				1	0	
	14. To exploit regional potentials				0			

16 Portugal

Policy profile of 1994/95

The Portuguese policy profile for the period 1994/95 is characterized by a weak engagement of some relevant policy areas in the development of biotechnology and a quite unbalanced consideration of the different areas of the biotechnology innovation system and the corresponding policy goals.

Regarding the policy areas, research and industrial development seem to be the only areas involved in supporting the biotechnology innovation system in the period 1994/95. Research policy mostly used biotechnology-specific instruments to promote biotechnology research. According to the sources used, instruments to support the industrial application of research results (exploitation policy), the regulatory framework and fiscal measures played a minor role.

Regarding the policy goals pursued to support the different areas and networks of the innovation system, the policy profile presents a focus on the promotion of the knowledge base, especially the promotion of basic research through biotechnology-specific instruments. On the industry side, business investment is a relatively strong policy goal, however public support seems to disregard knowledge transmission processes. Goals related to market processes are also neglected. Finally, regional potentials are not exploited.

Regarding the performance of the innovation system in the year 2002, all performance indicators are below the European average. Even though research policy is committed to promote biotechnology, the performance of the knowledge base is disappointing with publications and citations well below the average. Indicators for knowledge transmission, market and industry are also very weak. The weakness of the science base is probably the main source of weakness of the system. From this point of view using biotechnology-specific policy instruments to develop the knowledge base is the right policy option. However, according to the policy profile government support is probably not strong enough.

Policy profile of 2004

In 2004, Portugal dedicated more than 5 % of its national R&D budget to biotechnology. There are many sectors involved in the development of biotechnology but to different degrees. Pharmaceuticals are the most important, whereas laboratory equipment and supply is the least important. Chemicals and agro-food have an intermediate position.

The response to the questionnaire in 2004 shows that research, regulation and fiscal measures now seem to be the key policy areas to support the biotechnology innovation system. As in the previous period, policies boosting research are still the main focus of policy. This policy area uses mostly generic, as opposed to biotechnology-specific instruments to promote biotechnology research. Exploitation, industrial development and demand do not represent the core of the Portuguese policy emphasis in biotechnology.

Regarding the policy goals pursued to support the different areas and networks of the innovation system, the policy profile presents a focus on the promotion of the knowledge base across all types of biotechnology research (basic and applied) and disciplines. Education is important to ensure the availability of human resources regarding biotechnology competencies, but not managerial or entrepreneurial competencies. The core of support for knowledge transmission, commercialisation and industry development is made through regulatory and fiscal measures.

Dynamic changes in the policy profile

The overall evolution of the Portuguese policy profile shows continuity in its concentration on the knowledge base and the associated human resources. However, there has been a significant shift from biotechnology-specific to generic instruments for supporting research. There has also been a significant diversification of policy tools as compared with the previous time period with the use of regulatory and fiscal measures to encourage knowledge transmission, the market and industry. These measures previously played a minor role.

The poor performance of the knowledge base suggests that it may be premature for a shift to the higher priority now given to generic rather than biotechnology-specific policy instruments. This shift will do little to improve research performance. The introduction of regulatory and fiscal measures may improve market conditions and industrial performance, but for significant improvement there may be need to introduce exploitation and industrial development policies to address the market and industry, and especially to encourage firms in traditional sectors to exploit biotechnology.

Responses indicate that in Portugal, there is no direct or indirect assessment of the impact of biotechnology policies nor is there a formal coordination mechanism. European directives related to the patentability of biotechnology inventions, the use and commercialisation of GMOs have now been adopted. Protection for workers from risks related to biological agents is yet to be implemented.

Portugal 1994/95

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators: 2002 *or latest available year* 100 = EU Average
Knowledge base and human resources	1. To promote high level of biotechnology basic research		**1** **5**			**1**			O1. Publications **30** O2. Citations **58** O3. Graduates **n.a.**
	2. To promote high level of industry-oriented (and applied) research		**1** **3**						
	3. To support knowledge flow between scientific disciplines		**3** **0**						
	4. To assure availability of human resources	**n.d.**							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			**1** **0**		**2**			O4. Patents **3** O5.Companies **30**
	6. The adoption of biotechnology for new industrial applications						**0**	**n.d.**	
	7. To assist firm creation	**0**			**2** **0**	**0**	**2**		
Market	8. To monitor and improve the social acceptance of biotechnology							**n.d.**	O6. Accept. Index [31] **99,35** O7. Drug approvals **0** O8. Field Trials **25** O9. Production **87**
	9. To facilitate the introduction of new products					**0**			
	10. To strengthen the economic sectors exploiting biotechnology						**0**		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						**0**		
Industry	12. To encourage business investment in R&D				**3**		**2**		O10. IPOs **0** O11. Pub. Comp. **0** O12. VC in High Tech **20** O13. Venture Cap **24**
	13. To improve firm's competitiveness	**0**				**0**	**2**		
	14. To exploit regional potentials				**n.d.**				

31 EU Average is 100,29. See annex 5.

Portugal 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 3			3		
	2. To promote high level of industry-oriented (and applied) research		3 1					
	3. To support knowledge flow between scientific disciplines		5 3					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 0		4		
	6. The adoption of biotechnology for new industrial applications						3	0
	7. To assist firm creation	0			3 0	3	4	
Market	8. To monitor and improve the social acceptance of biotechnology							2
	9. To facilitate the introduction of new products					3		
	10. To strengthen the economic sectors exploiting biotechnology						3	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						3	
Industry	12. To encourage business investment in R&D				0		4	
	13. To improve firm's competitiveness	0				3	4	
	14. To exploit regional potentials				0			

17 Slovakia

Policy profile of 2004

The Slovakian policy profile shows that in 2004 Slovakia had mainly installed policies that support biotechnology research as well as education in biotechnology. In 2004, no policies that directly support the exploitation of biotechnology research or the industrial development in biotechnology existed. Neither had Slovakia public policies that stimulated the adoption of biotechnology by companies that are not performing biotech R&D themselves.

The policies Slovakia had installed for supporting education in biotechnology concern educational programmes in biotechnology on all levels: undergraduate degree, master degree, and doctorate. The programmes focus on biotechnology research only; modules on Business Administration in biotechnology are not provided.

Both generic and biotechnology-specific instruments support biotechnology basic research, applied research, as well as the international mobility of researchers. The generic instruments are considered as slightly more important than the biotechnology-specific instruments. Despite the presence of generic and specific instruments promoting biotechnology research, the public investments in biotechnology are estimated at below one percent of the national public R&D budget.

Although Slovakia does not have public policies that directly support the commercial exploitation of biotechnology research or the industrial development in biotechnology, the government uses fiscal policies and its regulatory framework to foster knowledge transmission and industrial development. Slovakia has tax incentives to promote innovation activities, but these mainly focus on the large firms and private investors; spin-offs and SMEs are considered as less important target groups. Regarding the regulatory framework, the intellectual protection of biotechnology inventions, also from public research organisations, is considered as rather important.

The regulatory framework conditions for company creation and firm growth are a priority for public authorities as well. In the design of regulations, sectors that are considered are especially the agro-food sector, followed by the chemical sector. The pharmaceutical and laboratory equipment sectors are considered as less important in this context.

Slovakia uses technology foresight studies and workshops to explore the benefits, costs and risks of the application of biotechnology. In these activities, only policy-makers, public research organisations and NGOs are involved. The industry and non-expert citizens are not involved, although workshops are organised to establish a dialogue between the various stakeholders, including industry and citizens. Issues that are considered in these demand-oriented activities include ethical, legal, economic, environmental, health and public perception aspects.

Mechanisms for policy impact assessment and policy coordination are not implemented in Slovakia.

Various EC directives have been implemented relatively quickly, these directives were not considered as very controversial.

Slovakia 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		3 2			2		
	2. To promote high level of industry-oriented (and applied) research		3 2					
	3. To support knowledge flow between scientific disciplines		2 2					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			0 0		4		
	6. The adoption of biotechnology for new industrial applications						5	0
	7. To assist firm creation	0			0 0	3	3	
Market	8. To monitor and improve the social acceptance of biotechnology							2
	9. To facilitate the introduction of new products					2		
	10. To strengthen the economic sectors exploiting biotechnology						5	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						5	
Industry	12. To encourage business investment in R&D				0		4	
	13. To improve firm's competitiveness	0				2	4	
	14. To exploit regional potentials				n.d.			

18 Slovenia

Policy profile of 2004

In 2004 Slovenia dedicated more than 5 % of the national public research and development budget to the promotion of biotechnology. At the time of gathering the relevant data for the policy profile Slovenia was going though strong institutional changes in what concerns the ministerial organization of education, science and technology policy. Furthermore, the government was in the process of preparing two important national strategies which should be launched by June 2005: the national research and development programme (2005-2009) and the national development programme for higher education (2006-2010).

According to the available information, in 2004 public policy targeted mainly one sub-area of the innovation system: the sub-area related to the knowledge base and human resources. The policy goals relevant for the other 3 sub-areas of the innovation system seem to be disregarded.

Regarding the policy areas engaged in the promotion of biotechnology, education and research policy have been the main resorts active in the promotion of biotechnology. Especially the area of education seems to be targeting very well the relevant policy goals. With the implementation of generic instruments, research policy is engaged in promoting basic and applied research. However, there seems to be an important policy gap in supporting the knowledge flow between scientific disciplines. The other relevant policy areas (exploitation, industrial development, regulation, fiscal and demand policy) are not active in the promotion of biotechnology. Small exceptions are generic instruments to promote technology transfer and firm creation. Also demand policy seems to be active in monitoring and improving biotechnology acceptance. The strongest policy gaps can be found in regulation and fiscal policy. The regulatory framework only considers the framework conditions relevant for conducting basic research.

In what concerns the processes of policy implementation Slovenia does not implement any specific mechanisms to asses the impacts of policy measures related to biotechnology. Formal mechanisms to coordinate policy instruments for the promotion of biotechnology (across ministries and/or regions) are also missing.

Given the policy profile for 2004 (and assuming that the biotechnology knowledge base in Slovenia currently has not reach a critical mass jet to enable the development of a biotechnology industry and the marketing of biotechnology-based products) the promotion of the biotechnology knowledge base exclusively through the implementation of generic instruments might not be enough. At this stage, biotechnology-specific promotion programmes are necessary to reach a suitable knowledge base. In this process, the focus should be on those areas of biotechnology that can fulfil the technological needs of the industrial sectors established in the country. In other words, the design of biotechnology promotion programmes to develop the knowledge base should consider the industrial sectors represented in the country. Additionally, an effort should be made to established suitable regulatory framework conditions for innovation activities in these industrial sectors.

Slovenia 2004

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 / 0			5		
	2. To promote high level of industry-oriented (and applied) research		5 / 0					
	3. To support knowledge flow between scientific disciplines		0 / 0					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			3 / 0		0		
	6. The adoption of biotechnology for new industrial applications						0	0
	7. To assist firm creation	5			2 / 0	0	0	
Market	8. To monitor and improve the social acceptance of biotechnology							3
	9. To facilitate the introduction of new products					0		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				0		0	
	13. To improve firm's competitiveness	5				0	0	
	14. To exploit regional potentials				1			

19 Spain

Policy profile of 1994/95

The Spanish policy profile for the period 1994/95 is characterized by weak involvement in relevant policy areas and policy gaps in three of the four areas of the innovation system. Regarding the policy goals, Spain considered only the very early stages of innovation process related to the development of the knowledge base and human resources. Among the policy areas education and research policy instruments are the core of the Spanish policy profile for the period 1994/1995. According to the available information the other policy areas are not especially engaged in promoting biotechnology. Generic instruments for the exploitation of biotechnology (especially in the case of industrial application of scientific results) play a minor role. The regulatory framework only tackles research issues.

Output indicators point to a performance below the average in most categories. Those indicators related to knowledge base and knowledge transmission are below or well below the European average. Indicators of industrial development are well below the average index too. However, on the market side, the output indicators are above the European average (except indicator O7 for drug approvals which takes a cero value).

Concerning the relation between policy goals, policy areas and output indicators, the following observations can be put forward:

- From a general viewpoint, one explanation of low levels of performance for 2002 might be the weak policy involvement for the period 1994/95 which may have long term effects. In addition there is a certain mismatch between rather high activities aiming at stimulating the availability of human resources and the low output of the system in terms of life sciences graduates.
- More specifically, on the market side, even though the indicator for field trials is above average, it may be misleading to conclude that Spanish innovation system is focused mainly on the agro food-related research. In terms of number of researchers and biotechnology companies as well as in terms of economic resources dedicated to research and development biotechnology in Spain is much focused on the health area (animal and human diagnostics and therapeutics) than in the agro-food area. Nevertheless, in 2002, no drug approvals had been listed.

Policy profile of 2004

In 2004 Spain dedicates more than 5 % of the national public R&D budget to biotechnology. The available information reveals strong commitment of policies for the development of the knowledge base and the commercial promotion of biotechnology.

In 2004 research policy targeted high level biotechnology basic research as well as-oriented research. Spanish policies put a strong emphasis on commercialization especially technology transfer from academia to industry and firm creation. Measures dedicated to encourage business investment in R&D have also received stronger emphasis in recent years. The Pharmaceutical sector is considered to be important, not the agro-food one.

Spain has implemented specific mechanisms to assess the impacts of policy measures related to biotechnology. The coordination between regional and national policy instruments is institutionalized through an inter-ministerial institutional forum / arena. The implementation process of various EC directives linked to biotechnology has been both fast and none controversial.

Dynamic changes in the policy profile

Higher education and research policies were the core of the Spanish profile in 1994/95. In 2004 this is still the case but other policy areas have emerged. The main change between 1994/95 and 2004 concern the market and industry areas of the innovation system. In 2004 Public policy towards biotechnology in Spain not only supports Small and Medium enterprises (SMEs) and firm creation. It also tends to attract and maintain large firms in Spain and to create a favourable environment for biotechnology.

Spain 1994/95

	Policy goals	Policy Area							Output Indicators
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	2002 *or latest available year* 100 = EU Average
Knowledge base and human resources	1. To promote high level of biotechnology basic research		2 0			2			O1. Publications **60** O2. Citations **72** O3. Graduates **92**
	2. To promote high level of industry-oriented (and applied) research		3 0						
	3. To support knowledge flow between scientific disciplines		2 0						
	4. To assure availability of human resources	5							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			2 0		1			O4. Patents **14** O5.Companies **9**
	6. The adoption of biotechnology for new industrial applications						0	0	
	7. To assist firm creation	0			0 1	1	1		
Market	8. To monitor and improve the social acceptance of biotechnology							1	O6. Accept. Index[32] **98,67** O7. Drug approvals **0** O8. Field Trials **135** O9. Production **140**
	9. To facilitate the introduction of new products					1			
	10. To strengthen the economic sectors exploiting biotechnology						0		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0		
Industry	12. To encourage business investment in R&D				0		0		O10. IPOs **0** O11. Pub. Comp. **0** O12. VC in Biotech **9** O13. Venture Cap **60**
	13. To improve firm's competitiveness	0				1	0		
	14. To exploit regional potentials				1				

32 EU Average is 100,29. See annex 5.

Spain 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 0			3		
	2. To promote high level of industry-oriented (and applied) research		4 0					
	3. To support knowledge flow between scientific disciplines		5 0					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 0		3		
	6. The adoption of biotechnology for new industrial applications						4	1
	7. To assist firm creation	1			4 0	2	1	
Market	8. To monitor and improve the social acceptance of biotechnology							3
	9. To facilitate the introduction of new products					1		
	10. To strengthen the economic sectors exploiting biotechnology						4	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						4	
Industry	12. To encourage business investment in R&D				4		4	
	13. To improve firm's competitiveness	1				1	4	
	14. To exploit regional potentials				1			

20 Sweden

Policy profile of 1994/95

The Swedish policy profile of the mid 1990s presents strong imbalances. Regarding the policy areas, education policy seems to be strongly committed to create qualified human resources. Concerning research policy, Sweden gives high priority to basic research but addresses all areas of the knowledge base through a combination of generic and biotechnology-specific instruments, with a strong emphasis on generic policy tools. The policy area "exploitation" is active in promoting the industrial application of biotechnology with biotechnology-specific instruments. Industrial development policy focuses mainly on the support of firm creation and seems to disregard industrial development in more mature phases of the industry life cycle. The regulatory framework tackles innovation aspects only at the early phases of the innovation process (knowledge base and knowledge transmission). Finally, fiscal measures and demand policy seem to be policy areas neglected by the Swedish policy-making system.

Regarding policy goals in the period 1994/95, the policy profile reveals a strong government commitment to supporting the development of the knowledge base with high priority for basic research through both generic and specific instruments. The policy goals related to knowledge transmission are also pursued especially with policies directed towards exploitation and industrial development. However, in this period the focus on these areas is less strong than for the knowledge base. Finally, market and industrial development are large gaps in the policy-making system.

On the performance side, the output indicators for the year 2002 reveal an above average performance of the innovation system in the development of the knowledge base. Apart from the number of graduates (which surprisingly lies well below the EU15 average), the bibliometric indicators (publications and citations) are above the average, especially the number of publications per capita. This speaks for the effectiveness of research policy and the regulatory framework in this area.

Regarding the output indicators for the knowledge transmission process, the indicators are above average, in both patents per capita and number of companies per capita, which again speak for an effective policy profile. On the market side the situation is not as positive. The number of drug approvals per capita and the volume of production in biotechnology relevant economic sectors are well below average. The biotechnology acceptance index does not reach the EU average. Only the number of field trials per capita outperforms the European average. Considering the important policy gaps in this area, these results are not surprising. Finally, on the industry side, the indicators available are satisfactory. Venture capital investors seem to have strong confidence in the Swedish biotechnology industry, even though the government concern for this area in the period 1994/95 seemed to be very weak.

Policy profile of 2004

In 2003, Sweden committed 1-3 % of the national public R&D budget to biotechnology. The only sector heavily engaged in the development of biotechnology is pharmaceuticals. There is less involvement in biotechnology by other sectors (chemicals, agro-food, environment-related activities (e. g. water and waste treatment), textiles and contract research organisations (dedicated biotechnology firms dedicated to the exploration and commercialisation of biotechnology).

The Swedish policy profile continues to present strong imbalances. Regarding the policy areas, education policy continues to be strongly committed to create qualified human resources. Concerning research policy, Sweden also continues to implement a combination of generic and biotechnology-specific instruments putting a strong weight on generic policy tools. Policy to promote exploitation is active in promoting the industrial application of biotechnology with generic instruments. Industrial development policy is generally weak and mainly supports firm creation and industrial investment in R&D. The regulatory framework tackles innovation aspects through all phases of the innovation process, whereas fiscal measures seem to be neglected by the Swedish policy-making system. Social acceptance is also an important area for policy as far as demand is concerned.

Regarding policy goals, the policy profile reveals a strong government commitment to the support of the development of the knowledge base. The policy goals related to knowledge transmission are also pursued in terms of exploitation, industrial development and especially regulatory policies. However, the focus is not as strong as in the case of the knowledge base. Finally, market and industrial development are big gaps in the policy-making system, although some efforts are now being made in this direction.

In Sweden, policy-makers are committed to the assessment of the impact of biotechnology policies, only after such policy has been completed. This mainly concerns the economic impact of biotechnology policy. Responses to the questionnaire indicate that there is no formal mechanism to coordinate biotechnology policies.

Dynamic changes in the policy profile

Over time, there has been only slight change in areas addressed by Swedish policy for biotechnology. The one exception is related to regulation which now has great weight in relation to the knowledge base, knowledge transmission, the market and industry. Similarly, policy goals have only changed at the margin, with slightly more or less emphasis being given to specific policies These small changes are likely to have minor impact only on Swedish performance.

Sweden 1994/95

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators: 2002 *or latest available year* 100 = EU Average
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 4			3			O1. Publications **204** O2. Citations **119** O3. Graduates **81**
	2. To promote high level of industry-oriented (and applied) research		2 3						
	3. To support knowledge flow between scientific disciplines		5 0						
	4. To assure availability of human resources	5							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			2 3		2			O4. Patents **176** O5.Companies **298**
	6. The adoption of biotechnology for new industrial applications						0	n.d.	
	7. To assist firm creation	n.d.			2 0	0	0		
Market	8. To monitor and improve the social acceptance of biotechnology							1	O6. Accept. Index[33] **100,34** O7. Drug approvals **65** O8. Field Trials **191** O9. Production **31**
	9. To facilitate the introduction of new products					0			
	10. To strengthen the economic sectors exploiting biotechnology						0		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0		
Industry	12. To encourage business investment in R&D				1		0		O10. IPOs **89** O11. Pub. Comp. **152** O12. VC in Biotech **192** O13. Venture Cap **222**
	13. To improve firm's competitiveness	n.d.				1	0		
	14. To exploit regional potentials				n.d.				

33 EU Average is 100,29. See annex 5.

Sweden 2004

	Policy goals	Policy Area						
		Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 3			5		
	2. To promote high level of industry-oriented (and applied) research		5 3					
	3. To support knowledge flow between scientific disciplines		4 3					
	4. To assure availability of human resources	4						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			4 1		5		
	6. The adoption of biotechnology for new industrial applications						0	n.d.
	7. To assist firm creation	0			2 1	5	0	
Market	8. To monitor and improve the social acceptance of biotechnology							4
	9. To facilitate the introduction of new products					5		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				3		0	
	13. To improve firm's competitiveness	0				5	0	
	14. To exploit regional potentials				1			

21 United Kingdom

Policy profile of 1994/95

According to the information available, the British policy profile showed weak policy dedication to the promotion of biotechnology in the period 1994/95. Additionally, in this period public support did not address important areas of the biotechnology innovation system.

Regarding the role of the different policy areas to promote biotechnology, education policy and generic policy instruments targeting basic research are the strongest instruments in the policy profile. The policy instruments for the commercial exploitation of research results and industrial development (both generic and specific policies) have a very low weight. The demand side also receives minor attention. Another important gap appears in the area of fiscal policy, which ignores most aspects of the innovation process.

Regarding the policy goals targeting the four areas of the innovation system, the promotion of basic research and the availability of qualified human capital are the only important targets. Knowledge transmission (or industrial application of biotechnology) is pursued through exploitation policy, industrial development and demand policies. However, policy commitment is quite weak. According to the sources used to produce the policy profile, market processes and industry competitiveness are areas of the innovation system not targeted by public promotion programmes or policy measures.

Compared to the European average the output indicators present a good performance in the development of the knowledge base and in the creation of human resources. However, as we move towards other areas of the innovation system (knowledge transmission and market) the results are weaker. For instance, the number of biotechnology patents per capita is only slightly above average and the number of biotechnology companies is below average. The market indicators are quite worrying as well (drug approvals and field trials are both below the European average). The biotechnology acceptance index is also below the European average.

The analysis represents a critical situation in the British biotechnology innovation system, where the actors seem to have problems in applying and in developing biotechnology in innovative products. Even though in comparison with the EU average the knowledge base output indicators are quite satisfactory, the overall results are worrying. The lack of policy engagement in the period 1994/95 in the promotion of industry-oriented research and the policy gaps in other areas could explain to some extent the weaknesses of the British biotechnology innovation system in 2002.

Policy profile of 2004

In 2004, the UK dedicated more than 5 % of its national R&D budget to biotechnology. There are many sectors heavily engaged in the development of biotechnology: pharmaceuticals, chemicals, agro-food, environment-related activities (e. g. water and waste treatment), textiles and contract research organisations (dedicated biotechnology firms dedicated to the exploration and commercialisation of biotechnology). Indeed, responses to the questionnaire reveal a strong commitment of policies to the development of the knowledge base and the commercial promotion of biotechnology.

Regarding the role of the different policy areas to promote biotechnology, it is being promoted by a variety of tools, both generic and specific. Research is a very strong area of policy. Education is also important as far as human resources are concerned. Regulation has received strong emphasis in recent years. Commercial exploitation, industrial development and fiscal measures receive a lower weight. As in the previous period, there is a gap in the area of fiscal policy, which ignores some aspects of the innovation process.

Regarding the policy goals targeting the four areas of the innovation system, the promotion of basic research and the availability of qualified human capital are the most important targets, even though education policy seems to downplay the necessary managerial and economic content in the curricula of students to support firm creation. The reason for this is that in the UK, policy for curricula content is in the hands of individual universities. Therefore, there is no centralised mechanism for policy to emphasise managerial and economic content. Knowledge transmission (or industrial application of biotechnology) is pursued through exploitation, regulation, industrial development and demand policies.

In the UK, policy-makers, universities and industrial organisations are committed to the assessment of the impact of biotechnology policies. This concerns economic, environmental and ethical aspects, the formation of geographic (regional) clusters and cost-benefit analysis. This is accompanied by formal mechanisms to coordinate biotechnology policies, both in a geographic sense (e. g. national coordination of regional policies) and in terms of objectives (education, science, industry, etc.). This coordination is organised at the all levels (ministries, inter-ministerial cabinet, and independent boards). All European directives related to biotechnology (patentability of biotechnology inventions, use of GMOs, commercialisation of GMOs, protection of workforce) have been adopted with high-speed and with no or little controversy.

Dynamic changes in the policy profiles

The greatest area of dynamic change in the British policy profile appears to be connected to regulation. As there is no data on regulation for the previous period the significance of this change is not clear. Nevertheless, regulation now has high priority as a policy measure connected with the knowledge base, knowledge transmission, the market and industry. Other instruments to promote commercial exploitation and industrial development receive a lower weight. As in the previous period, there is a gap in the area of fiscal policy, which ignores some aspects of the innovation process.

The changes in policy do not seem adequate to make significant improvement to weak British performance in commercial exploitation of research results and industrial development. The commercial exploitation of the strong British knowledge base currently relies mainly on grants to establish technology transfer offices at universities. Future improvement may depend on the introduction of a broader range of instruments to encourage entrepreneurial scientists and promote spin-off companies e. g. mentoring entrepreneurial academic scientists in business skills and providing grants for start-up companies.

United Kingdom 1994/95

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators: 2002 *or latest available year* 100 = EU Average
Knowledge base and human resources	1. To promote high level of biotechnology basic research		0 5			n.d.			O1. Publications **143** O2. Citations **134** O3. Graduates **306**
	2. To promote high level of industry-oriented (and applied) research		0 1						
	3. To support knowledge flow between scientific disciplines		0 0						
	4. To assure availability of human resources	4							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			1 2		n.d.			O4. Patents **113** O5.Companies **83**
	6. The adoption of biotechnology for new industrial applications						0	1	
	7. To assist firm creation	0			2 1	n.d.	2		
Market	8. To monitor and improve the social acceptance of biotechnology							2	O6. Accept. Index[34] **98,11** O7. Drug approvals **98** O8. Field Trials **69** O9. Production **119**
	9. To facilitate the introduction of new products					n.d.			
	10. To strengthen the economic sectors exploiting biotechnology						0		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0		
Industry	12. To encourage business investment in R&D				0		0		O10. IPOs **373** O11. Pub. Comp. **420** O12. VC in Biotech **119** O13. Venture Cap **294**
	13. To improve firm's competitiveness	0				n.d.	0		
	14. To exploit regional potentials				n.d.				

34 EU Average is 100,29. See annex 5.

United Kingdom 2004

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand
Knowledge base and human resources	1. To promote high level of biotechnology basic research		5 5			5		
	2. To promote high level of industry-oriented (and applied) research		5 5					
	3. To support knowledge flow between scientific disciplines		5 0					
	4. To assure availability of human resources	5						
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			3 2		5		
	6. The adoption of biotechnology for new industrial applications						0	3
	7. To assist firm creation	2			2 3	5	3	
Market	8. To monitor and improve the social acceptance of biotechnology							4
	9. To facilitate the introduction of new products					5		
	10. To strengthen the economic sectors exploiting biotechnology						0	
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						0	
Industry	12. To encourage business investment in R&D				3		3	
	13. To improve firm's competitiveness	2				5	3	
	14. To exploit regional potentials				0			

22 United States

Policy Profile of 1994/95

In 1994 the United States had already a strong biotechnology science base and was a leader in the commercialisation of biotechnology.

The policy profile for the period 1994/95 presents a quite balanced combination of the different policy areas. 12 Federal Agencies were involved in fostering biotechnology research and commercialization. Research policy concentrated mostly on health-related research, which was a national priority. Accordingly the federal investment in biotechnology focused primarily on the health field (41 % of the federal funding in 1994). Exploitation policy was implemented through generic instruments for technology transfer, focusing especially on fostering collaborative research between industry and public research institutions. Exploitation policy was complemented with regulatory framework conditions fostering the patenting of research results from universities. Further more generic policy measures for industrial development supported SMEs in co-financing R&D projects. Fiscal incentives for innovation were implemented already in the 1980s. The research and experimentation (R&E) tax credit rewards firms that are rapidly increasing their R&D investments. Specially SMEs benefit from this measure.

Regarding the policy goals, all aspects of the national innovation system are taken into consideration. In 1994 the policy strategy aims at sustaining the US leadership in biotechnology by enhancing the support of the biotechnology knowledge base and by trying to identify fields of biotechnology application other than the health field. All 3 output indicators for the performance of the Knowledge base outperform the European average in 2000, specially the quality and training indicator (O2 and O3).

Concerning the policy goals targeting knowledge transmission (goals 5 to 7), biotechnology-specific measures play a minor role in fostering the application and commercialization of biotechnology. According to the output indicators, the US outperforms its European counterparts in patenting; however the number of companies per capita in 2002 is below the European average.

Efforts to improve efficiency of the markets for biotechnology products tackle the supply and the demand side. In this context, the output indicators for market performance are very much above the European average, especially the indicator related to the development of biotechnology-related products in the agricultural sector (Indicator O8).

Finally, at the level of the industry, the output indicators show the strong dynamics of the biotechnology industry and the capital markets in comparison with the European performance.

Policy Profile of 1994/95

	Policy goals	Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators (Type / National / Reference)
Knowledge base and human resources	1. To promote high level of biotechnology basic research		4 4			n.d.			O1. Publications **121** O2. Citations **171** O3. Graduates **171**
	2. To promote high level of industry-oriented (and applied) research		4 5						
	3. To support knowledge flow between scientific disciplines		n.d. n.d.						
	4. To assure availability of human resources	4							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			3 0		4			O4. Patents **170** O5.Companies **75**
	6. The adoption of biotechnology for new industrial applications						3	n.d.	
	7. To assist firm creation	0			3 2	4	3		
Market	8. To monitor and improve the social acceptance of biotechnology							3	O6. Accept. Index **n.d** O7. Drug approvals **231** O8. Field Trials **698** O9. Production **65**
	9. To facilitate the introduction of new products					4			
	10. To strengthen the economic sectors exploiting biotechnology						3		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						3		
Industry	12. To encourage business investment in R&D				4		4		O10. IPOs **411** O11. Pub. Comp. **656** O12. VC in Biotech **575** O13. Venture Cap **321**
	13. To improve firm's competitiveness	0				4	4		
	14. To exploit regional potentials				n.d.				

23 Canada

Policy Profile of 1994/95

The Canadian policy profile reflects the first National Biotechnology Strategy introduced in 1983 and still in place in the mid 1990s. The main goal of that strategy was to foster the development of a biotechnology R&D capacity in Canada. In addition, an advisory body for biotechnology was established (National Biotechnology Advisory Committee (NBAC)). The task of the NBAC was to advise the minister of industry on the economics and industrial aspects of biotechnology. In 1993 the strategy was complemented by the “Principles of the Federal Regulatory Framework for Biotechnology”. Accordingly, research policies and regulation policies comprise the main policy activities of the Canadian biotechnology profile. Education and exploitation policies did not play a predominant role in the middle of the 1990s. With respect to industrial development mainly generic policies aimed at assisting firm creation. A number of generic instruments was also applied for various fiscal policy initiatives. On the demand side biotechnology-specific policies supported studies and analyses of socio-economic issues of biotechnology. It is interesting to note that later in the 1990s with the new Canadian Biotechnology Strategy of 1998 Canada started to collect systematically statistical information on biotechnology.

In line with the Canadian policy profile most of the biotechnology-related policy goals aiming at supporting the knowledge base and human resources were well in the focus of various policy activities. Policy goals related to knowledge transmission, on the other hand, were not supported to that extent by policy measures. On the market side mainly generic fiscal measures were implemented supporting the various market-related policy goals. Also with respect to industrial development mainly generic policies had been implemented.

The output indicators related to the knowledge base and human resources present above average performance of Canada. Obviously, a main policy goal of the middle of the 1990s – to foster the development of a biotechnology R&D capacity in Canada – has been achieved. Output indicators for knowledge transmission present a mixed picture of the Canadian performance. In terms of patent applications Canada is performing below average, while in terms of biotechnology companies Canada is outperforming the average. Similarly, output indicators related to the market present no clear picture. In terms of drug approvals and production volumes the respective data present below average performance. On the other hand, Canada is performing extraordinarily with respect to the number of field trials. Indicators for industrial development also present a very good performance of Canada.

Policy Profile of 1994/95

	Policy goals	Policy Area: Education	Research	Exploitation	Industrial development	Regulation	Fiscal measures	Demand	Output Indicators (Type / National / Reference)
Knowledge base and human resources	1. To promote high level of biotechnology basic research		3 4			3			O1. Publications **132** O2. Citations **129** O3. Graduates **196**
	2. To promote high level of industry-oriented (and applied) research		3 2						
	3. To support knowledge flow between scientific disciplines		0 0						
	4. To assure availability of human resources	1							
Knowledge transmission	5. To facilitate transmission of knowledge from academia to the industry and its application for industrial purposes			1 1		5			O4. Patents **91** O5.Companies **197**
	6. The adoption of biotechnology for new industrial applications						0	n.d.	
	7. To assist firm creation	0			4 0	4	4		
Market	8. To monitor and improve the social acceptance of biotechnology							3	O6. Accept. Index **n.d.** O7. Drug approvals **37** O8. Field Trials **834** O9. Production **94**
	9. To facilitate the introduction of new products					4			
	10. To strengthen the economic sectors exploiting biotechnology						4		
	11. To keep/attract large firms (important market, important for firm development: tacit knowledge etc.)						4		
Industry	12. To encourage business investment in R&D				3		4		O10. IPOs **198** O11. Pub. Comp. **616** O12. VC in Biotech **928** O13. Venture Cap **267**
	13. To improve firm's competitiveness	0				4	4		
	14. To exploit regional potentials				2				

Annex 5: Output indicators

Output Indicator 1: Biotechnology publications

	1995	1996	1997	1998	1999	2000	2001	2002	Total 1995-2000	ptC	Index	
Austria	557	612	703	721	772	718	:	:	6804	0,51	88	**Austria**
Belgium	1122	1066	1198	1172	1225	1171	:	:	11201	0,68	118	**Belgium**
Denmark	857	900	956	1027	1062	1029	:	:	10043	1,09	190	**Denmark**
Finland	671	598	664	711	804	789	:	:	7360	0,82	142	**Finland**
France	5454	5740	5773	6056	6110	5865	:	:	53625	0,60	103	**France**
Germany	6324	6786	6896	7310	7562	7201	:	:	64664	0,51	89	**Germany**
Greece	232	269	263	289	273	307	:	:	2652	0,15	26	**Greece**
Ireland	262	289	235	316	335	305	:	:	3159	0,46	80	**Ireland**
Italy	2602	2791	2800	3035	3088	3125	:	:	26991	0,30	52	**Italy**
Luxembourg	7	14	8	16	10	14	:	:	109	0,16	28	**Luxembourg**
Netherlands	2281	2157	2289	2213	2355	2204	:	:	21122	0,85	148	**Netherlands**
Portugal	236	252	268	259	362	399	:	:	2970	0,17	30	**Portugal**
Spain	2044	2236	2134	2368	2531	2454	:	:	21465	0,34	60	**Spain**
Sweden	1575	1658	1761	1811	1872	1737	:	:	17009	1,18	204	**Sweden**
UK	8345	7864	7979	8378	8286	8363	:	:	75067	0,83	143	**UK**
US	32054	32054	31991	32199	32459	31962	:	:	290038	0,70	121	**US**
Canada	3969	4016	3803	3834	4041	3758	:	:	35815	0,76	132	**Canada**
EU 15 Average										0,58	100	**EU 15 Average**

Source: Biotechnology Innovation Scoreboard (BIS)

p t C: per thousand capita

Output Indicator 2: Citations to biotechnology publications

	1995	1996	1997	1998	1999	2000	2001	2002	Total 1995-2000	Cit. per BT publ.	Index	
Austria	12014	9342	8448	6504	3588	433	:	:	49390	7,26	116	**Austria**
Belgium	21388	18798	14719	9997	4645	678	:	:	82407	7,36	117	**Belgium**
Denmark	17347	12722	11211	8456	4084	597	:	:	69308	6,90	110	**Denmark**
Finland	13846	10230	9719	6099	2994	463	:	:	55191	7,50	120	**Finland**
France	102605	88946	70023	51921	23514	4016	:	:	374360	6,98	111	**France**
Germany	136991	119893	96424	70274	35180	5935	:	:	511468	7,91	126	**Germany**
Greece	2781	2248	1622	1266	565	298	:	:	10448	3,94	63	**Greece**
Ireland	3095	2720	2318	2413	1200	160	:	:	16419	5,20	83	**Ireland**
Italy	40298	35767	27917	21377	10532	1615	:	:	152037	5,63	90	**Italy**
Luxembourg	64	110	37	71	37	8	:	:	372	3,41	54	**Luxembourg**
Netherlands	48700	35228	31166	20541	10115	1688	:	:	168535	7,98	127	**Netherlands**
Portugal	2625	1980	1807	1487	836	140	:	:	10721	3,61	58	**Portugal**
Spain	22754	22916	18251	13439	7211	1318	:	:	96567	4,50	72	**Spain**
Sweden	31770	27135	24355	14891	7486	1150	:	:	127474	7,49	119	**Sweden**
UK	185542	137342	120875	82716	41080	7434	:	:	633147	8,43	134	**UK**
US	917854	740083	594496	403109	192592	32450	:	:	3116079	10,74	171	**US**
Canada	81308	68335	52723	37410	18251	2658	:	:	290060	8,10	129	**Canada**
EU 15 Average										6,27	100	**EU 15 Average**

Source: Biotechnology Innovation Scoreboard (BIS)

Cit. Per publ.: Citations per biotechnology publication

Output Indicator 3: Graduate PhD students (tertiary programmes for further education/ theoretically based programmes and advanced research programmes) in life sciences

	1995	1996	1997	1998	1999	2000	2001	2002	Number of graduates (2001 or last year availiable)	pmC	Index	
Austria	:	:	:	:	622	549	636	:	636	79	53	**Austria**
Belgium	:	:	:	733	806	2020	1970	:	1970	192	128	**Belgium**
Denmark	:	:	:	:	627	647	683	:	683	128	85	**Denmark**
Finland	:	:	:	389	511	526	481	:	481	93	62	**Finland**
France	:	:	:	0	2031	24272	2529	:	2529	43	29	**France**
Germany	:	:	:	5977	6491	6170	6410	:	6410	78	52	**Germany**
Greece	:	:	:	:	:	:	:	:	:	:	:	**Greece**
Ireland	:	:	:	1529	884	1882	1729	:	1729	452	301	**Ireland**
Italy	:	:	:	9306	5561	5612	6684	:	6684	116	77	**Italy**
Luxembourg	:	:	:	0	0	0	:	:	0	0	0	**Luxembourg**
Netherlands	:	:	:	839	780	842	817	:	817	51	34	**Netherlands**
Portugal	:	:	:	:	:	492	:	:	:	:	:	**Portugal**
Spain	:	:	:	4439	4843	5356	5579	:	5579	138	92	**Spain**
Sweden	:	:	:	1614	813	886	1081	:	1081	122	81	**Sweden**
UK	:	:	:	16015	16561	23488	27527	:	27527	460	306	**UK**
	:	:	:									
US	:	:	:	75253	77090	74597	71497	:	71497	257	171	**US**
Canada				8469	8904	9164	:	:	9164	295	196	**Canada**
EU 13 Average										150	100	**EU 13 Average**

Source: OECD

p m C: per million capita
: not availiable

Output Indicator 4: Biotechnology patent applications at the European Patent Office

	1995	1996	1997	1998	1999	2000	2001e	up to 3rd Quart. 2002e	Total 1995-2002	ptC	Index	
Austria	31	44	51	46	68	70	85	44	440	0,05	102	**Austria**
Belgium	76	79	109	152	177	131	127	69	920	0,09	166	**Belgium**
Denmark	80	106	104	128	126	143	146	81	914	0,17	317	**Denmark**
Finland	38	29	33	41	47	46	52	28	314	0,06	112	**Finland**
France	229	235	302	368	404	427	454	231	2650	0,04	83	**France**
Germany	382	470	559	653	840	982	984	634	5504	0,07	124	**Germany**
Greece	2	1	2	2	7	7	19	4	44	0,00	7	**Greece**
Ireland	13	10	16	29	21	22	28	16	155	0,04	74	**Ireland**
Italy	67	82	93	90	104	121	118	85	760	0,01	25	**Italy**
Luxemburg	0	1	1	1	1	2	1	0	7	0,02	29	**Luxemburg**
Netherlands	130	132	158	182	179	241	186	129	1337	0,08	154	**Netherlands**
Portugal	0	1	3	1	5	5	3	2	19	0,00	3	**Portugal**
Spain	20	35	34	32	64	43	55	32	315	0,01	14	**Spain**
Sweden	77	84	105	117	128	141	124	70	846	0,09	176	**Sweden**
UK	299	360	513	542	578	494	515	283	3584	0,06	113	**UK**
US	2797	3137	3215	3398	3215	3398	5729	1516	26405	0,09	170	**US**
Canada	124	161	198	225	234	206	281	115	1544	0,05	91	**Canada**
EU 15 Average										0,05	100	**EU 15 Average**

Source: Own calculations drawn on Data from the online databases EPAT and PCTPAT (Vendor Questel). June 2004

Comments: The data for 2001 and 2002 are estimations. The year 2002 includes the number of patent applications up to the third quartal of the year.

Output Indicator 5: Number of biotechnology companies (public and private)

	1995	1996	1997	1998	1999	2000	2001	2002	2002 or Last availiable year	pmC	Index	
Austria						59			59	7	109	**Austria**
Belgium		35	44	55	62	65		69	69	7	99	**Belgium**
Denmark		28	45	52	68	64		75	75	14	207	**Denmark**
Finland		30	46	51	74	77		76	76	15	217	**Finland**
France		101	132	145	175	177	226	239	239	4	60	**France**
Germany	75	104	173	222	279	332	365	360	360	4	65	**Germany**
Greece	*	*	*	*	*	*		*	*			**Greece**
Ireland		26	38	40	43	31		35	35	9	133	**Ireland**
Italy		32	42	44	48	52		51	51	1	13	**Italy**
Luxemburg	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.			**Luxemburg**
Netherlands		50	63	65	75	85		85	85	5	78	**Netherlands**
Norway		16	25	25	25	28		21	21	2	30	**Norway**
Spain		15	23	23	23	25			25	1	9	**Spain**
Sweden		65	88	98	125	165		179	179	20	298	**Sweden**
UK		180	248	265	274	275		331	331	6	83	**UK**
US	1308	1287	1274	1283	1311	1273	1457	1466	1466	5	75	**US**
Canada							416	417	417	13	197	**Canada**
EU 14 Average										7	100	**EU 14 Average**

Source: Ernst and Young European Life science Reports, several years

* less than 5

Output Indicator 6: Biotechnology Acceptance Index

	Index Average
Austria	100,89
Belgium	100,59
Denmark	101,18
Finland	100,18
France	101,12
Germany (West)	101,70
Germany(East)	100,41
Greece	101,05
Irland	100,28
Italy	100,58
Luxemburg	101,58
Netherlands	101,29
Portugal	99,35
Spain	98,67
Sweden	100,34
UK*	98,11
US	n.a.
Canada	n.a.
EU - 15**	100,29

* Without North Irland

** Weighted Average according to the weigt "W13" of the Eurobarometer 58.2, which considers population differences among countries and corrects for inconsistencies in the national samples.

Source: Own calculations. The biotechnology acceptance index draws on the the Questions Q.12 (encouragement aspect) , Q.13.1, Q14.01 and Q14.09 of the Eurobarometer 58.0.

Output Indicator 7: Number of bio-medicines approved by the EMEA** or the FDA*

	1995	1996	1997	1998	1999	2000	2001	2002	1995-2002	pmC	Index	
Austria**	0	0	0	0	0	0	0	0	0	0,00	0	**Austria****
Belgien**	0	0	0	0	0	0	0	0	0	0,00	0	**Belgien****
Denmark**	0	1	0	0	1	1	0	8	11	2,05	1190	**Denmark****
FInland**	0	0	0	0	0	0	0	0	0	0,00	0	**FInland****
France**	0	0	3	0	1	3	3	0	10	0,17	98	**France****
Germany**	1	0	0	0	1	2	3	0	7	0,08	49	**Germany****
Greece**	0	0	0	0	0	0	0	0	0	0,00	0	**Greece****
Irland**	0	0	0	0	0	0	0	0	0	0,00	0	**Irland****
Italy**	0	0	0	0	0	0	0	0	0	0,00	0	**Italy****
Luxemburg**	0	0	0	0	0	0	0	0	0	0,00	0	**Luxemburg****
Netherlands**	0	0	0	0	0	0	0	0	0	0,00	0	**Netherlands****
Portugal**	0	0	0	0	0	0	0	0	0	0,00	0	**Portugal****
Spain**	0	0	0	0	0	0	0	0	0	0,00	0	**Spain****
Sweden**	0		0	0	0	0	1	0	1	0,11	65	**Sweden****
UK	0	2	2	0	1	3	1	1	10	0,17	98	**UK**
US*	5	14	15	15	11	17	14	24	115	0,40	231	**US***
Canada*	1	0	0	0	0	1	0	0	2	0,06	37	**Canada***
EU 15 Average										0,17	100	**EU 15 Average**

Source: own calculations. Raw data from FDA* internet site and EMEA annual reports**

*FDA Approvals
**EMEA Approvals
pmC: per million capita

Output Indicator 8: Number of field trial-traits

	1995	1996	1997	1998	1999	2000	2001	2002
Austria								
Belgium								
Denmark								
Finland								
France								
Germany								
Greece								
Ireland								
Italy								
Luxemburg								
Netherlands								
Norway								
Spain								
Sweden								
UK								
US								
Canada	127	132	122	185	139	178	146	96
EU 14 Average								

1996-2001	pmC	Index	
3	0,37	11	**Austria**
69	6,72	193	**Belgium**
25	4,67	134	**Denmark**
22	4,25	122	**Finland**
397	6,72	193	**France**
102	1,24	36	**Germany**
23	2,10	61	**Greece**
4	1,05	30	**Ireland**
245	4,24	122	**Italy**
n.a.	n.a.		**Luxemburg**
43	2,69	77	**Netherlands**
9	0,88	25	**Norway**
189	4,68	135	**Spain**
59	6,64	191	**Sweden**
144	2,41	69	**UK**
6745	24,26	698	**US**
902	28,99	834	**Canada**
	3,48	100	**EU 14 Average**

Source: BIS, Canadian Food Inspection Agency
pmC: per million capita

Output Indicator 9: Production volume in million PPS in economic sectors relevant for the application of biotechnology*

	1995	1996	1997	1998	1999	2000	2001	2002	Total 1995-1999 Mio PPS	PPS / pC	Index	
Austria**	22488	23105	24244	24990	26858	30620	29820	23702	121685	15244	76	**Austria**
Belgium**	48712	49789	54444	55259	55173	67751	312	332	263378	25786	128	**Belgium**
Denmark	2571	2637	2777	2704	2883	3170	3316	3188	13571	2554	13	**Denmark**
Finland	27413	27323	30374	30398	30925	34684	34176	27710	146433	28381	141	**Finland**
France	255989	265077	290353	297924	307622	336540	350998	16475	1416965	24223	120	**France**
Germany	253525	266971	283371	283086	294181	334952	340648		1381135	16836	84	**Germany**
Greece	56755	54955	51527	49677	49191	49495	44399	46835	262105	24132	120	**Greece**
Irland	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a	n.a.	n.a.		**Irland**
Italy	234966	228208	232932	237415	241101	256279	243883	70621	1174621	20388	101	**Italy**
Luxembourg	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a	n.a.	n.a.		**Luxembourg**
Netherlands	84310	87183	92127	53473	54265	63446	25803	n.a.	371358	23563	117	**Netherlands**
Portugal	35728	35442	35702	34990	35638	n.a.	n.a.	n.a	177500	17488	87	**Portugal**
Spain	246656	260849	266858	272644	276931	n.a.	n.a.	n.a	1323939	33328	166	**Spain**
Sweden	10929	10812	10952	10845	11350	10631	10533	n.a.	54889	6199	31	**Sweden**
UK	274323	283535	290878	271312	267208	283490	n.a.	n.a.	1387256	23358	116	**UK**
US**	640793	662758	716356	753935	773632	800290	790836	n.a.	3547474	13060	65	**US**
Canada	104358	112109	116360	117838	125671	143501	n.a.	n.a.	576336	18891	94	**Canada**
EU 13 Average										20114	100	**EU 13 Average**

Source: OECD STAN Database, May 2004

* Sectors considered as relevant for the application of biotechnology:
Agriculture, hunting and forestry, Food products and beverages, Textiles, pulp, paper and paper products, chemicals excluding pharmaceuticals, pharmaceuticals, medical, precission and optical instruments

**Please note that US, Austria and Belgium figures do not include production in Agriculture

PPS . Purchasing Power Standard
pC: per Capita

Output Indicator 10: Initial public offerings (IPOs) per Biotechnology Company

	1995	1996	1997	1998	1999	2000	2001	2002	Total 1996-2002	P BT Company in 2002	Index	
Austria									0	0,00	0	**Austria**
Belgium		1							1	0,01	46	**Belgium**
Denmark		2		1		2			5	0,07	211	**Denmark**
Finland						1			1	0,01	42	**Finland**
France		3	2	2					7	0,03	93	**France**
Germany		2	1		5	10			18	0,05	158	**Germany**
Greece									0	0,00	0	**Greece**
Ireland		1							1	0,03	91	**Ireland**
Italy		2				2			4	0,08	249	**Italy**
Luxemburg									0		0	**Luxemburg**
Netherlands				1	1	1	1		4	0,05	149	**Netherlands**
Portugal									0		0	**Portugal**
Spain									0	0,00	0	**Spain**
Sweden			2			3			5	0,03	89	**Sweden**
UK	5	11	5	4	2	10	3	4	39	0,12	373	**UK**
US	20	50	24	21	15	68	6	6	190	0,13	411	**US**
Canada		9	2	1	1	8	2	3	26	0,06	198	**Canada**
EU 15 Average										0,03	100	**EU 15 Average**

Source: E&Y Annual European Life Sciences Reports, websites by Nasdaq, Neuer Markt, London Stock Exchange, Toronto Stock Exchange, Euronext, BIO

p BT Company: per biotechnology company

Output Indicator 11: Number of biotechnology public companies

	1995	1996	1997	1998	1999	2000	2001	2002
Austria								0
Belgium								1
Denmark								5
Finland								1
France								6
Germany							12	13
Greece								0
Ireland								2
Italy								1
Luxemburg								0
Netherlands								3
Portugal								0
Spain								0
Sweden								9
UK								46
US	260	294	317	316	301	342	342	318
Canada			59			77	85	85
EU 15 Average								

2002	p BT company	Index	
0	0,00	0	**Austria**
1	0,01	44	**Belgium**
5	0,07	202	**Denmark**
1	0,01	40	**Finland**
6	0,03	76	**France**
13	0,04	109	**Germany**
0	0,00	0	**Greece**
2	0,06	173	**Ireland**
3	0,06	178	**Italy**
0	0,00	0	**Luxemburg**
3	0,04	107	**Netherlands**
0	0,00	0	**Portugal**
0	0,00	0	**Spain**
9	0,05	152	**Sweden**
46	0,14	420	**UK**
		0	
318	0,22	656	**US**
85	0,20	616	**Canada**
		0	
	0,03	100	**EU 15 Average**

Source: Ernst and Young European Life science Reports, several years. BioteCanada

p BT Company: per Biotechnology Company

Output Indicator 12: Venture Capital invested in biotechnology (1000 PPS)

	1995	1996	1997	1998	1999	2000	2001	2002	Total 1995-2002 1000 PPS	PPS / pC	Index	
Austria	0	0	0	1673	763	0	5276	229	7941	1	12	**Austria**
Belgium	9161	12309	20630	3488	31617	26213	34659	34021	172098	17	206	**Belgium**
Denmark	1240	1793	2516	3718	5294	38468	28438	39668	121136	23	279	**Denmark**
Finland	851	1861	839	8196	6540	12926	4655	7696	43564	8	104	**Finland**
France	23741	16781	26053	10077	39082	145384	65844	120452	447415	8	93	**France**
Germany	11597	47726	50595	120175	190310	386171	320188	144022	1270785	15	190	**Germany**
Greece	0	0	0	0	0	0	0	0	0	0	0	**Greece**
Ireland	0	3508	2837	1153	190	82	0	1665	9435	2	30	**Ireland**
Italy	2001	35	6	6	12084	14271	5590	3624	37615	1	8	**Italy**
Luxemburg	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	**Luxemburg**
Netherlands	11315	9415	25707	20346	23734	34440	15143	62013	202115	13	155	**Netherlands**
Portugal	2338	0	0	0	926	0	0	0	3264	0	4	**Portugal**
Spain	0	51	7318	322	2931	9526	411	8443	29002	1	9	**Spain**
Sweden	0	304	851	1230	7521	8547	22689	97522	138663	16	192	**Sweden**
UK	46073	67094	59945	81011	126405	52991	40479	93750	567748	10	119	**UK**
Canada	51469	142388	183124	212337	289144	619483	445668	261299	2204912	70	928	**Canada**
US	601047	878564	1095328	1160784	1663322	3256938	2485713	2291060	13432755	47	575	**US**
EU 14 Average										8	100	**EU 14 Average**

Source: EVCA, MoneyTree Survey of the NVCA, CVCA and own calculations

PPS: Purchasing power parity standard
pC: per Capita
n.a. not available

Output Indicator 12'[35]: Venture Capital invested in high technology sectors (1000 PPS)

	1995	1996	1997	1998	1999	2000	2001	2002	Total 2001-2002	PPS / pC	Index	
Austria			0	12533	22821	73468	55846	54580	110426	14	67	**Austria**
Belgium			111203	73669	250776	221235	75538	79802	155339	15	74	**Belgium**
Denmark			7486	14455	30030	94406	93806	71938	165744	31	151	**Denmark**
Finland			25528	31565	93066	136963	92699	83773	176471	34	166	**Finland**
France			218465	313437	636575	2136842	656437	510611	1167049	20	96	**France**
Germany			28038	54774	1041052	1928200	1175942	538710	1714652	21	102	**Germany**
Greece			0	0	0	0	9276	6079	15355	1	7	**Greece**
Ireland			20147	32504	47669	140784	97476	48464	145940	37	183	**Ireland**
Italy			35310	112403	351074	587591	944496	323563	1268059	22	109	**Italy**
Luxemburg			n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0	0	0	**Luxemburg**
Netherlands			120500	162895	281207	259765	94906	213200	308106	19	94	**Netherlands**
Portugal			0	0	62372	49918	26643	16114	42758	4	20	**Portugal**
Spain			54602	116323	90940	398638	245970	85952	331922	8	40	**Spain**
Sweden			46589	90850	179680	247097	175466	101018	276485	31	152	**Sweden**
UK			824435	1272624	1498623	1570588	942148	717919	1660068	28	138	**UK**
Canada												**Canada**
US												**US**
EU 14 Average										20	100	**EU 14 Average**

Source: EVCA and own calculations

PPS: Purchasing power parity standard

35 Due to problems with data availability, this indicator is used for Portugal and Greece instead of the venture capital investment in biotechnology

Output Indicator 13: Total Venture Capital invested (1000 PPS)

	1995	1996	1997	1998	1999	2000	2001	2002	Total 2001-2002	PPS / pC	Index	
Austria			0	12533	22821	73468	55846	54580	110426	14	67	**Austria**
Belgium			111203	73669	250776	221235	75538	79802	155339	15	74	**Belgium**
Denmark			7486	14455	30030	94406	93806	71938	165744	31	151	**Denmark**
Finland			25528	31565	93066	136963	92699	83773	176471	34	166	**Finland**
France			218465	313437	636575	2136842	656437	510611	1167049	20	96	**France**
Germany			28038	54774	1041052	1928200	1175942	538710	1714652	21	102	**Germany**
Greece			0	0	0	0	9276	6079	15355	1	7	**Greece**
Ireland			20147	32504	47669	140784	97476	48464	145940	37	183	**Ireland**
Italy			35310	112403	351074	587591	944496	323563	1268059	22	109	**Italy**
Luxemburg			n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0	0	0	**Luxemburg**
Netherlands			120500	162895	281207	259765	94906	213200	308106	19	94	**Netherlands**
Portugal			0	0	62372	49918	26643	16114	42758	4	20	**Portugal**
Spain			54602	116323	90940	398638	245970	85952	331922	8	40	**Spain**
Sweden			46589	90850	179680	247097	175466	101018	276485	31	152	**Sweden**
UK			824435	1272624	1498623	1570588	942148	717919	1660068	28	138	**UK**
Canada												**Canada**
US												**US**
EU 14 Average										20	100	**EU 14 Average**

Source: EVCA and own calculations

PPS: Purchasing power parity standard
pC: per Capita
n.a. not availiable

Population

in million (1st January)

	1995	1996	1997	1998	1999	2000	2001	2002	
Austria	7,94	7,95	7,97	7,97	7,98	8,00	8,02	8,04	**Austria**
Belgium	10,13	10,14	10,17	10,19	10,21	10,24	10,26	10,31	**Belgium**
Denmark	5,22	5,25	5,28	5,29	5,31	5,33	5,35	5,37	**Denmark**
Finland	5,10	5,12	5,13	5,15	5,16	5,17	5,18	5,19	**Finland**
France	57,75	57,94	58,12	58,30	58,50	58,75	59,04	59,34	**France**
Germany	81,54	81,82	82,01	82,06	82,04	82,16	82,26	82,44	**Germany**
Greece	10,60	10,67	10,74	10,81	10,86	10,90	10,93	10,99	**Greece**
Ireland	3,60	3,62	3,65	3,69	3,73	3,78	3,83	3,90	**Ireland**
Italy	57,27	57,33	57,46	57,56	57,61	57,68	57,84	56,99	**Italy**
Luxemburg	0,41	0,41	0,42	0,42	0,43	0,43	0,44	0,44	**Luxemburg**
Netherlands	15,42	15,49	15,57	15,65	15,76	15,86	15,99	16,11	**Netherlands**
Portugal	10,01	10,04	10,07	10,11	10,15	10,20	10,26	10,33	**Portugal**
Spain	39,31	39,38	39,47	39,57	39,72	39,96	40,38	40,85	**Spain**
Sweden	8,82	8,84	8,84	8,85	8,85	8,86	8,88	8,91	**Sweden**
UK	58,50	58,70	58,91	59,09	59,39	59,62	59,86	59,14	**UK**
Canada	29,44	29,79	30,11	30,43	30,51	30,79	31,11	31,41	**Canada**
US	261,69	264,16	266,49	269,11	271,63	275,56	278,06	288,60	**US**

Source: EUROSTAT

Purchasing Parity Standards:

1 PPS in national currency / Euro fixed for Euro-zone countries

		1995	1996	1997	1998	1999	2000	2001	2002	
EU	Eu	1,00	1,00	1,00	1,00	1,00	1,00	1,00	1,0	**EU**
Austria	Eu	1,07	1,05	1,04	1,04	1,02	1,00	1,01	1,0	**Austria**
Belgien	Eu	1,04	1,03	1,03	1,03	1,03	1,00	0,99	1,0	**Belgien**
Denmark	Danish Krone	9,68	9,55	9,49	9,45	9,18	9,15	9,19	9,4	**Denmark**
FInland	Eu	1,10	1,08	1,06	1,08	1,07	1,07	1,07	1,1	**FInland**
France	Eu	1,08	1,06	1,03	1,03	1,01	1,00	0,99	1,0	**France**
Germany	Eu	1,16	1,13	1,12	1,11	1,10	1,07	1,07	1,1	**Germany**
Greece	Eu	0,65	0,68	0,71	0,74	0,74	0,75	0,76	0,8	**Greece**
Irland	Eu	0,92	0,92	0,92	0,97	1,01	1,04	1,08	1,1	**Irland**
Italy	Eu	0,87	0,89	0,89	0,89	0,88	0,88	0,90	0,9	**Italy**
Luxemburg	Eu	1,13	1,12	1,13	1,12	1,07	1,08	1,10	1,1	**Luxemburg**
Netherlands	Eu	1,02	1,01	1,00	1,01	1,01	1,01	1,01	1,0	**Netherlands**
Portugal	Eu	0,69	0,70	0,71	0,72	0,71	0,71	0,72	0,7	**Portugal**
Spain	Eu	0,80	0,80	0,81	0,81	0,80	0,81	0,82	0,8	**Spain**
Sweden	Swedish Krone	10,62	10,40	10,39	10,49	10,20	10,01	10,28	10,4	**Sweden**
United Kingdom	Pound Sterling	0,70	0,70	0,69	0,70	0,70	0,69	0,69	0,7	**United Kingdom**
Canada	Can. Dollar	1,13	1,12	1,11	1,11	1,09	1,08	1,09	1,08	**Canada**
US	US Dollar	1,38	1,36	1,34	1,32	1,30	1,30	1,30	1,29	**US**

Source: Eurostat

1 PPS in national currency / Euro fixed for Euro-zone countries

Annex 6: Case Studies

Annex 6.1: Benchmarking of public biotechnology policies: A case study report of VIB's technology transfer activities

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25 January 2005[36]

1. Introduction

The project 'Benchmarking of public biotechnology policies' (Polybench project) aims, among others, at improving the understanding of the impact of public policies on biotechnology and at developing methods for measuring this impact. For specific policy areas where no suitable indicators can be defined a priori, case studies can be useful in order to elucidate the relationship between policies and impact in more detail. It was mentioned in the PolyBench project proposal that a case study aiming at performing an in-depth analysis of best practice technology transfer in biotechnology could provide important hints for designing respective policies.

In Europe it is widely acknowledged that an excellent science base is not a guarantee for excellent commercial performance. The lack of ability to turn scientific strength into innovative and commercially viable applications is generally referred to as the innovation paradox or in Europe as the European Paradox (among others: Allansdottir et al. 2002 and European Commission 2002). In order to deal with this innovation paradox, public policy instruments are widely introduced as a means to stimulate the commercialisation of technology. Technology transfer instruments are used and they can come in many different forms. Roessner (2000:1) gives a very broad definition of technology transfer, which can include many different types of technology transfer: "the movement of know-how, technical knowledge, or technology from one organisational setting to another". An overview of commercialisation instruments in biotechnology, based on the recent EPOHITE study (Reiss et al. 2003), shows that, in general, two types of technology transfer initiatives can be distinguished (Enzing et al. 2005):

- Instruments that support the commercialisation of scientific results from public research institutions: e. g. spin-off formation, technology transfer offices for patenting and licensing, science parks and incubators.

36 This is the revised version of the case study (according to the comments from DG Enterprise on the version of October 2004).

- Instruments that support collaboration between public and industrial research: e. g. research programmes requiring industry involvement, support of temporary personnel exchange between industry and public research organisations.

An analysis of commercialisation instruments in biotechnology, also based on the EPOHITE study, shows that technology transfer instruments aiming at commercialising public sector biotech research exist in all 14 European Member States (Enzing et al. 2004). However, EPOHITE also showed that in most countries the instruments for supporting technology transfer were not working very well. Both scientists and representatives from firms interviewed for the EPOHITE study gave rather negative assessments of the technology transfer organisations in their countries. These observations are supported by an OECD study (2003) that highlighted the barriers many technology transfer organisations in the public sector encounter, resulting in lower degrees of efficiency and effectiveness in technology transfer. Nevertheless, EPOHITE also reported some positive exceptions such as the Flanders Interuniversity Institute for Biotechnology (VIB) in Belgium and BioResearch Ireland.

In this case study report we will examine in more detail the organisation and performance of VIB in the area of technology transfer. We will also discuss the factors that play a critical role in the successful performance of VIB. The case study report is based on desk research, an interview with Prof. dr. Rudy Dekeyser, Head of the Technology Transfer Unit and Vice General Director at VIB, and on interviews in the EPOHITE project with eight Belgian researchers and companies, of which five are actually involved in VIB.

2. The Flanders Interuniversity Institute for Biotechnology – VIB

The Flemish government decided in 1995 to strengthen the Flemish expertise in life sciences and to turn the results into new economic growth by establishing VIB. Instead of physically integrating various research groups on one place, the Flemish government decided to provide structural, long-term funding by combining competences in a virtual institute, in which research is performed at a number of the Flemish universities (http://www.vib.be). VIB has its head quarters in Zwijnaarde (near Ghent).

For the first period (1996-2000/1) VIB received from the Flemish government a subsidy of approximately 267 million € (Little 2001). For the second period (2001/2-2006) the Flemish government provided a basic funding of 140 million €. In addition to the basic funding from the Flemish government, VIB also receives funding from other resources, such as IWT-Flanders, EU-programmes , contract research for industry, services, international research programmes, university funding, as well as personal funding for individual scientists. In 2003, the total operating income amounted to more than 41 million €, including 28.6 million € basic funding (VIB Annual report 2004: activities of VIB in 2003).

In 2003, the total workforce of VIB amounted to 865 employees (823 full-time equivalents), including 59 group leaders, 451 pre- and post-doctoral co-workers, 318 technicians and supporting personnel, and 37 staff members at VIB headquarters (VIB Annual report 2004: activities of VIB in 2003).

The Flemish government assigned three main tasks to VIB:

- Performing and supporting strategic basic research;
- Stimulating and facilitating technology transfer, and;
- Providing biotechnology education and information to the general public.

The tasks related to research and education/information are described in sections 2.1 and 2.2. The technology transfer activities will be presented in more detail in chapter 3.

Flanders, one of the three regions of Belgium, counts approximately 30 dedicated biotechnology companies. Most companies are active in the area of human health. More than 15 companies have been established after 1995. In 2002, the dedicated biotechnology companies employed over 1,600 people.

Biotechnology research started in the early 1970s at Flemish research groups in particular at the University of Ghent and the Catholic University Leuven. Flemish research groups are traditionally active in both human health and agricultural biotechnology.

Biotechnology has been a priority to the Flemish government since the 1990s. According to estimations of Arthur D. Little (2001), the Flemish government has invested more than 496 million € in biotechnology in the period 1991-2000.

2.1 Strategic basic research

VIB's research is performed in 60 research groups located in nine research departments of four universities (Ghent University, Catholic University Leuven, University of Antwerp, and Free University of Brussels). The research covers the fields of molecular biology, cell biology, developmental biology, structural biology, systems biology, genetics, biochemistry, microbiology, genomics and proteomics. VIB's main objective is to understand the mechanisms that are responsible for normal growth and development, and for diseases (http://www.vib.be).

The research departments develop a long-term strategic plan to define their mission, long-term focus, and the research questions they will address. International science advisory boards regularly review the research. VIB and the four universities jointly finance the research budget, which amounted to 52 million € in 2003 (VIB Annual report 2004: activities of VIB in 2003). Approximately 40 % of this research budget is financed from VIB's own budget, 60 % is financed from research grants.

In 2003, the total number of articles in peer reviewed journals amounted to 308 articles, of which 176 were published in the highest ranked journals. This was 20 % more than in 2002 and 159 % more than in 1996. In 2003, 39 PhD students completed their thesis (VIB Annual report 2004: activities of VIB in 2003).

2.2 Information and education

VIB is also explicitly assigned to provide the general public with clear and scientifically based information about biotechnology in all its facets. VIB has developed many initiatives to inform different stakeholders, such as press, scholars and students, politicians, laymen, and school teachers. VIB operates as an expertise and information centre which receives many requests from the public for information. Furthermore, VIB publishes brochures, computer presentations, books, newsletters, dossiers, and press bulletins. In addition, VIB actively participates in workshops, panels, seminars, and conferences. VIB also organises exhibitions on biotechnology. The website, http://www.vib.be, is the portal to information about VIB, biotechnology, applications, and socio-economic, legal and environmental aspects of biotechnology.

Under the first operating agreement with the Flemish government (1996-2001) VIB had initiated a research programme on the social and ethical impact of biotechnology. The objective of the programme was to investigate relevant societal questions and ethical issues dealing with biotechnology that would become important in the future. Another objective was to bring together biotechnology and the social sciences. In 1999, seven projects started, lasting from two to four years (http://www.vib.be).

In 2003, together with six European partners, VIB started ECOD-BIO, a pan-European network of communication officers in biotechnology. The aim of this network is to develop and evaluate new communication strategies (VIB Annual Report 2004: Activities of VIB in 2003).

3. Technology transfer at the VIB

As stated, technology transfer of biotechnology knowledge and expertise to industry is one of the three tasks assigned to VIB. In 1997, VIB developed its technology transfer policy. VIB aims to translate the results of VIB research into industrial applications, together with the industry, with the ultimate goal to realize more healthcare and food products for society. Other objectives are generating income to foster the VIB research and bringing together the scientists and the life sciences industry (http://www.vib.be).

VIB's technology transfer policy includes three main tasks:

- Identifying inventions with commercial potential;
- Securing the necessary property rights;
- Marketing the technology through executing agreements with companies (licensing) and the foundation of start-ups, including a special fund for financing commercially promising research projects.

(http://www.vib.be)

In addition, VIB initiated other technology transfer activities, which are open to non-VIB scientists and companies as well. These activities include:

- Incubator facilities for biotechnology companies;
- FlandersBio, the development of a high-competitive biotechnology cluster;
- VIBdeTECHTor, an electronic newsletter for Flemish biotechnology companies;
- Coordinating joint international representation of Flemish biotechnology companies.

The VIB technology transfer unit employs 10 persons. Most of them have a PhD in life sciences and are experienced in business and legal affairs. They are expected to be capable of communicating with both the research and the industry community and of bringing the two together. Moreover, all need to be familiar with the Flemish system, culture and habits.

The annual budget for the technology transfer activities amounts to 2.5 million €, of which 80 % is dedicated to the three main tasks and 20 % to the additional technology transfer activities.

The following three sections describe the VIB three technology transfer activities in more detail. In section 3.4 the additional activities are presented.

3.1 Identifying inventions with commercial potential

In the technology transfer unit of VIB three employees are continuously trying to identify results from VIB's research activities that could have commercial potential. This scouting function is performed in close collaboration with the VIB researchers themselves and covers all research fields of VIB. Examples of inventions are a new medical application of a specific protein, a new method to stimulate the growth of crops, and a new technology to compare protein profiles of healthy and sick tissue. In 2003, 54 inventions have been identified, which brings the total number of inventions since the start of VIB at 369 (VIB Annual Report 2004: Activities of VIB in 2003).

Within VIB there has been established a culture of close and direct communication between the researchers and the technology transfer unit. Already in a very early stage the researchers and the technology transfer team discuss what interesting inventions could come out of the research. They do this because it is of utmost importance to identify patenting opportunities of research results as soon as possible as the European patenting system does not allow a grace period like in the United States.

The contracts between the central management of VIB and the research departments at the universities include a specific policy on technology transfer. The directors of the research departments and the principal researchers in these departments are explicitly held responsible for both publishing and patenting of research. This means that they are expected to contact the VIB technology transfer unit whenever new inventions occur and that they provide full cooperation with the technology transfer unit for in protecting these inventions. Awareness and a proactive attitude of the researchers are created and developed in course of time.

In order to stimulate the patenting of research results, VIB operates two incentive measures. First, VIB researchers are entitled to some part of the returns of patented research results. And second, the evaluation of VIB researchers is also based on their technology transfer output[37].

3.2 Securing property rights

After identification of a commercially interesting invention, an in-depth prior art investigation is started by VIB, concentrating on the novelty of the invention, its actual innovativeness and the opportunities for patent claims. For doing so, the technology transfer unit has full access to all relevant data sources. The filing of the patent starts as soon as the prior art investigation seems successful. Approximately 45 % of the inventions is transferred into a patent application (VIB Annual Report 2004: Activities of VIB in 2003). The VIB researchers are closely involved from day one, as they can help the technology transfer unit to identify the uniqueness and competing inventions of the research results under investigation.

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37 Their performance is evaluated on the basis of their publication output (60 %), their technology transfer output (30 %) and on training PhD students (10 %).

Approximately 30 patent applications are started each year. As soon as the patent application procedure has begun, the series of investigations are repeated several times, especially before the PCT and national phases. New information about competing inventions can occur, also because during the first 18 months of a patent application nothing will be published. Approximately one quarter of the patent applications is withdrawn during this procedure. Table A.6.1.1 shows the patent portfolio of VIB in 2003.

Table A.6.1.1 VIB's patent portfolio in 2003

Number of patent applications in 2003	**30**
Total number of active patent families 1995-2003	143
- in national phase	50 %
- in PCT phase	25 %
- in priority year	25 %
Total number of granted patents 1995-2003	39

Source: VIB Annual Report 2004: Activities of VIB in 2003

Approximately 15 % of the patent portfolio is patented because of strategic reasons; these patents will not be licensed out. These patents are, for example, needed to build up a patent portfolio for a new start-up.

The directors of the research departments and the principal researchers are not only made responsible for identifying the inventions, but also for cooperating with the technology transfer unit in patenting the inventions. The division of responsibilities and tasks, as well as the division of returns is laid down in the contracts between VIB and the research departments hosted by the universities. The technology transfer unit of VIB manages and exploits the patents and takes care of the costs. The official patent applicants are the VIB central organisation and the universities where the research for the invention was performed. If a patent results in a financial return, first VIB will reimburse the costs made for that patent. The distribution of the returns after reimbursement of the costs between research institutes and researchers is presented in table A.6.1.2.

The research institutes are the central organisation of VIB, the VIB research departments and the universities. The return distributes to the research institutes is divided in 80 % for the VIB research department, 10 % for the university that hosts the research department and 10 % for the central organisation of VIB.

Table A.6.1.2 Division of returns on VIB patents

Size of return	**Receivers of returns**	
	Research institutes	Researchers
< 6,250 €	100 %	0 %
6,250 € <> 62,500 €	60 %	40 %
62,500 € <> 625,000 €	80 %	20 %
> 625,000 €	90 %	10 %

Source: interview with R. Dekeyser

3.3 Research and IPR agreements with companies and the foundation of start-ups

The VIB technology transfer unit takes care of all the contracts and agreements between VIB, the VIB research departments and external parties. These contracts include both research contracts with research funding organisations, such as the EU, as well as research and commercialisation contracts with companies. The contracts with the industry include licensing, R&D collaboration, contract research, as well as first option agreements. VIB approaches the industry proactively and searches for companies that could be interested in collaboration, licensing or contract research.

An important source for industrial contacts is the researcher as they have large networks and know the markets and competition very well. More than half of the deals with companies are based on relations and suggestions of the researchers. The returns of the contract and agreements with companies are shared among VIB, the research departments and the researchers similar to the system described before.

All contracts and agreements with industry are tailor made and therefore different from each other. In collaborations with industrial parties a number of difficulties are persistent:

- Defining the value of the technology, as it often becomes clear only in the long term;
- Dividing the rights of intellectual property and related returns;
- Judging of what still needs to be developed and the costs related to it;
- Choosing the jurisdiction to which the contract will be drawn up.

Table A.6.1.3 presents the main characteristics of the industrial agreements and collaborations in 2003.

Table A.6.1.3 Industrial agreements and collaborations in 2003

Number of collaboration and licensing agreements in 2003	**47**
Turnover from collaboration agreements in 2003	3.3 million €
Number of collaboration and licensing agreements 1995-2003	183
- collaborations with other Flemish partners	44 %
- collaborations with European partners	28 %
- collaborations with US partners	28 %

Source: VIB Annual Report 2004: Activities of VIB in 2003

Licensing agreements are made for 48 % of the patent applications in the national phase, 26 % in the PCT phase and 17 % in the priority year. (VIB Annual report 2004: activities of VIB in 2003).

Another strategy VIB follows to commercialise research results is by establishing start-ups. So far, three start-ups have been set-up. In 1997, Devgen was established. Since 1997, it has generated 37 million € in three different rounds of financing. At the moment it employs 100 people (http://www.devgen.com). In 1998, CropDesign started. It has generated over 46 million € in three different rounds. Currently, CropDesign employs over 70 people (http://www.cropdesign.com). In 2001, Ablynx was established. The company generated 30 million € of financing in only three years time. Ablynx employs approximately 30 people (http://www.ablynx.com). A fourth start-up is being prepared at the moment.

The three start-ups are all heavily venture capital backed. The general process for establishing a start-up starts with seed funding from VIB. VIB invests this seed funding in an invention (or a set of inventions) to further develop the technology and to realise a proof of concept. This financing is invested in extra research at the VIB departments with the aim to build a technology platform, which can be protected by patents. In addition, the money is also used to internalise for instance by licensing-in technology owned by other parties. For example, VIB invested in two years 1.7 million € for the development of a technology platform prior to establishing Ablynx. This allowed Ablynx to start with 8 patent families and 40 patent applications as well as granted patens. The idea is to create a freedom to operate. Approximately half of VIB's budget for technology transfer activities available is allocated to this seed funding.

The next step in the process of starting a new business is preparing a business plan and attracting international investors. VIB aims to set up companies that can develop into sustainable companies with a critical mass of 30 to 40 employees in approximately two years time. This requires significant financial investments of at least 5 million € to 10 million € in the initial two to three years, which can only be provided by venture capitalists. A priority for VIB is to attract investors and venture capitalists with a good reputation, as this is necessary for successfully realising future rounds of financing.

In addition, VIB is highly involved in attracting and selecting the start-up's senior management team as they are aware of the value of a well-experienced management team for attracting investors. Furthermore, VIB also supports the due diligence research of the potential investors as well as setting up the day-to-day operations.

The fourth start-up, which is in preparation at the moment, will be established a bit differently. Instead of venture-capital, the new start-up will be backed by three industrial contracts. Venture capital is increasingly difficult to attract nowadays, but industrial contracts concerning collaborations, supplies and sales can support the start-up in developing in-house R&D. In addition, VIB supports the new start-up with investments in kind by setting-up facilities, worth 1 million €.

In general, VIB is heavily involved in the whole process from invention to the establishment of the start-up. VIB becomes shareholder of the company and has a seat in the Board of Directors. The financial investments by VIB are kept limited to the provision of seed capital. Not investing in later stages is a well-considered decision, as VIB wants to establish sustainable start-ups, which need to be backed by substantial financial investments. Such substantial investments are considered only to be possible for large, professional investors. After the start-up, the direct involvement of VIB ends except for the shareholding position and in the case of research collaborations. If wanted, the start-up can still make use of the services of VIB. Furthermore, the exit strategy is not defined by VIB, but by the company and the other investors.

3.4 Other technology transfer activities

VIB does not only initiate activities for the VIB research groups and companies; VIB is now supposed to stimulate and facilitate biotechnology developments in Flanders in general. For this VIB has initiated several technology transfer activities. The most important are the bio-incubator facility and FlandersBio.

Since 2000, VIB has a bio-incubator facility of 3,750 m^2. This bio-incubator is located in Ghent, at the Ghent Technology Park. The bio-incubator offers both laboratory and office facilities to young R&D intensive biotechnology companies, as well as R&D departments of established companies. In 2003, six companies made use of the incubator. In 2003, the Flemish government awarded VIB a grant of 3 million € for building another bio-incubator facility of 8,000 m^2 (http://www.vib.be).

In 2003, VIB initiated FlandersBio. FlandersBio aims to develop a high-competitive Flemish cluster of biotechnology companies and research organisations, by:

- stimulating the transfer of technological and non-technological knowledge and experiences between actors;
- improving the international profile of the Flemish biotechnology sector;
- building and supporting a favourable environment for the development of life sciences companies.

At the end of 2003, almost all Flemish biotechnology companies were a member of FlandersBio.

4. What explains the success of the VIB technology transfer activities?

Based on the technology transfer output VIB can be considered as rather successful in translating its basic research results into commercially attractive applications.

Summarizing the technology transfer performance of VIB:

- Each year 50 to 60 inventions are identified. This means that for every million Euro VIB is investing in research, one commercially interesting invention is identified. Public research organisations in the US need almost USD 2.5 million for one serious invention (AUTM, 2004).
- About 30 patent application procedures are started annually. VIB currently manages a patent portfolio consisting of 143 active patent families.
- VIB has established over 180 collaborative agreements with industrial partners from Belgium, Europe and the US. These agreements resulted in a turnover of 3.3 million €in 2003.
- The VIB technology transfer activities have resulted in three start-ups since 1997 and one being prepared. Although being a relatively small group of start-ups, the constituting companies have been able to develop into sustainable biotechnology companies with significant numbers of employees, IPR portfolio's and backed with large sums of private capital from major venture capitalists.
- The extent of success is also highlighted by the rather limited annual budget (2.5 million €) VIB has for its technology transfer activities.

In the EPOHITE project (Reiss et al. 2003) Flemish researchers and companies were asked to giver their own assessment of several policy instruments, including VIB. The researchers as well as the companies were very positive about the technology transfer office of VIB. What they assessed as very positive are VIB's pro-active attitude and the high qualified officers that advice and support the researchers. The availability of seed-money for spin-offs, based upon commercial benchmarks is also considered as beneficial.

So what could explain this success? What are the factors that enable VIB to reach this high level of technology transfer outcomes?

We have identified the following factors, which we consider as being critical in the process of technology transfer:

- Closeness to research;
- Combination of specific expertise fields in the VIB technology transfer team;
- Explicit technology transfer responsibilities in all levels of the VIB organisation;
- Considering of the entire value chain in technology transfer;
- Involvement and stimulation of researchers;
- Long-term and realistic vision on start-ups.

Closeness to research

One of the most important factors is the very small distance between the VIB technology transfer unit and the VIB research departments. The technology transfer unit is continuously scanning the research activities by three full-time ‘scouts’. There are very open communication channels between the scouts and the VIB researchers. In this way, the technology transfer unit obtains a sound picture of the VIB research activities and the opportunities for transfer and commercialisation.

Combination of expertise areas

It has been reported in several publications that an important barrier to efficient and effective technology transfer units in public research organisations is the lack of expertise that is necessary in addressing all elements of the technology transfer process (e. g. Reiss et al. 2003, OECD 2003). More in specific, this implies that a combination of expertise in the specific science and technology fields, legal affairs, and business-related aspects like financing, negotiating, writing business plans et cetera has to be available in the technology transfer units.

The members of the VIB technology transfer unit all have a scientific background in biotechnology (or related areas), but are also highly experienced in business and commercialising research. Therefore, they know what aspects need to be covered, how to build bridges between the research and industrial communities and how to communicate with potential clients.

Explicit responsibilities for technology transfer

Another important factor is that each level in the VIB organisation is made responsible for technology transfer, not only the VIB technology transfer unit, but also the research directors and the researchers themselves. The formal arrangements that are made force the research directors to focus strongly on the commercial potential of their research and to collaborate with the technology transfer unit. Furthermore, the inclusion of technology transfer activities as a main indicator for the individual assessment of the researchers' performance stimulates them to think in terms of commercialisation of research, in addition to publication. Last but not least, the explicit technology transfer tasks assigned to VIB by the Flemish government forces VIB to put technology transfer on the strategic agenda of the organisation. In this way, all levels in the VIB organisation bear the responsibility of technology transfer, which stimulates the development of an organisational culture aiming at technology transfer while reducing the risks of free-rider behaviour.

Considering the entire technology transfer value chain

A characteristic of the VIB technology transfer activities is that they address all relevant stages of the technology transfer value chain: from the identification of inventions to the appropriation of intellectual property rights and finally the commercialisation through licensing agreements, collaborations and spin-offs. By covering all these stages, VIB is following a broad vision on and approach to technology transfer, involving structural and substantial investments and a long-time horizon. This significantly increases the chances of commercially attractive research really ending up in financial returns through licensing agreements or in the creation of spin-offs. We expect technology transfer activities being less effective when the value chain is partly covered, for instance when the focus is only on the protection of research without the explicit intention of exploiting the IPRs.

Involvement and stimulation of researchers

The VIB technology transfer unit considers the researcher as an indispensable link in the technology transfer process. Researchers know their research project best and they have an excellent view on the innovative value of the outcomes. Moreover, they play an important role in for instance realising research collaborations, licensing agreements, between VIB and other parties, as they know who are also active in their field of research and are involved in the research networks. Besides getting involved by the technology transfer team in the tech transfer process from the beginning, researchers are also stimulated to think in terms of commercialising their research as they are also evaluated on their commercial performance through the reward schemes that are used in VIB. The schemes offer the individual scientists that have played an important role in the patenting of research results financial rewards when the patent is licensed or sold. In this way, scientists are increasingly stimulated to support valorisation processes of their research.

Long-term and realistic vision start-ups

An interesting characteristic of VIB is that it seems not to be interested in realising large numbers of start-ups as in other national biotech programmes in Europe, such as the BioRegio programme in Germany and the BioPartner programme in The Netherlands. Instead, VIB prefers to concentrate its efforts and resources on creating a selective number of start-ups with the potential of developing quickly into medium sized biotechnology companies. On first instance, they provide seed capital in order to support the development of an invention into a proprietary technology platform or to internalise externally owned technologies. VIB also offers legal and financial advice. Furthermore, VIB supports the company in preparing a business plan, in recruiting the senior staff of the company, and in attracting major venture capitalists. This is all done with the idea to create sustainable biotechnology companies that have an attractive and well protected patent portfolio, strongly backed by venture capitalists and that are able to reach a size of 40 employees in two years time.

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Annex 6.2: Policy approaches in Europe to support biotechnology adoption by established companies

Case studies within the project "Benchmarking of Public Biotechnology Policy" for the European Commission, DG-E

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Table of Contents

1. Introduction

Following a report of the OECD on applications of biotechnology for industrial sustainability, the adoption of biotechnology can provide retrenchments for a firm in either operation costs, capital costs or both. Furthermore the adoption of biotechnology allows for a significant relief of environmental strain by reducing wastewater, greenhouse gas production and the need for energy and water resources, (OECD, 2001).

It is estimated that industrial biotechnology could be a 100 billion US$ business by 2010 (Sterling, 2004). This figure illustrates the relevance of industrial applications of biotechnology. Already today, biotechnology plays an important role in established industries to reduce waste, to comply with environmental regulations, or to substitute conventional, less efficient techniques.

The support of the commercial exploitation of biotechnology is one of the targets of innovation policy in most industrialized countries.

The EPOHITE project, which analyzed biotechnology policies in 14 EU Member States (Reiss et al. 2003) found out that since 1994 most European countries have implemented a broad variety of different policies aiming at supporting the development of the biotechnology knowledge base, commercial utilization of biotechnology, and creating suitable framework conditions for biotechnology. With respect to the commercialization of biotechnology, a focus of such policies has been the support of knowledge transfer via firm creation. Ongoing work within this policy benchmarking project could confirm these EPOHITE findings. On the other hand, recent research indicates that the macro-economic impact arising from such a bio-industry in a narrow sense is limited (Menrad et al. 2003). According to the latter report, the economical impact of the adoption of biotechnology by established industries (measured e. g. as number of jobs depending on biotechnology) can exceed biotechnology's direct impact via biotechnology firms by an order of magnitude.

Against this background, an alternative and complementing way of promoting the development and diffusion of biotechnology is the support of biotechnology adoption by established companies. Applications can be found in nearly all industrial sectors – the most obvious ones are the pharmaceutical sector, the agro-food sector, the chemical sector and the environmental sector.

The term biotechnology adoption is the micro-economical counterpart of the broader process of biotechnology diffusion through the industry. The latter relates to the aggregate result of companies adopting and hence implementing the innovative technology. Adoption refers therefore to the companies' individual decision and implementation process (Lissoni and Metcalfe 1994, Stoneman 2002).

This case study explores the process of biotechnology adoption by established firms and current European public promotion programmes supporting this process. As this case study shows, policy approaches promoting biotechnology adoption are currently very rare. The next chapter presents possible motivations of established companies to adopt biotechnology. It tries to identify the needs of established companies in the adoption process. General policy instruments to support adoption of biotechnology by established companies are introduced in chapter 3, together with some example schemes. Finally, chapter 4 discusses in more detail one of the most comprehensive approaches in Europe to support the adoption of biotechnology by established companies.

In this report, supportive measures upstream of adoption processes like for example the promotion of basic research are not detailed. However, it is acknowledged that the industrial application of biotechnology draws on the development of the biotechnology knowledge base.

2. Biotechnology adoption by companies in established industries

The adoption of biotechnology by established companies can principally lead to

(1) the substitution of production processes

(2) and to the generation of new products.

Generally speaking, biotechnological processes can be introduced to substitute single or multiple conventional production steps, where a transformation of feedstock is needed. Such transformations usually rely on harsh physical-chemical conditions like high temperature, pressure and solvents, bases or acids. In contrast, biotechnology mostly works under mild physiological conditions. Besides the partial improvement of the production process of a given product, biotechnology can also alter the quality and added-value of a product, and even give rise to a completely new product.

2.1 Relevant economic sectors

Many industry branches already have a long track of the use of biotechnological processes.

In first place we consider the **agro-food sector**, where processes like the fermentation of beer and wine, the processing of bread and diary products or the production of food additives like amino acids and vitamins are carried out with the help of micro-organisms. There are also many applications for enzymes like proteases (meat processing), pektinases (fruit juice clarification), glucose isomerases (production of fructose), lactases (removal of lactose from milk). Many additives like preservatives and flavours are produced by biotechnological means. A further application is the development of functional foods, i. e. food with beneficial nutritional values for a healthier diet. Some new traits of functional foods, or plant production systems for pharmaceutical compounds, have been announced for market entry. In agricultural production agro-chemical companies make use of biotechnology for developing genetically modified seeds for herbicide or stress tolerance and pest resistance.

The **pharmaceutical sector** applies the so called "red biotechnology" as a research tool but also as a new production technology. Drugs and vaccines can be produced with genetically modified organisms; furthermore, countless active compounds from living organisms are still to be explored. Today, the development of most current drug leads implies the use of biotechnology. Diagnostics based on new techniques like bio-chips and antibodies are already established tools in the healthcare system.

A large number of **traditional industries** can profit from the application of the so called "white biotechnology". This term refers to the "application of modern biotechnology for the industrial production of chemical substances and bio-energy, using living cells and their enzymes, resulting in inherently clean processes with minimum waste generation and energy use" (BACAS, 2004). According to EuropaBio, a European association of commercial biotechnology stakeholders, white biotechnology includes applications of bio-based chemicals (leading to food ingredients, pharmaceuticals and fine chemicals), biomaterials (like polymers), and biofuels (e. g. bio-ethanol and biologically produced hydrogen). Some examples of this approach are discussed in the following:

In the chemical sector in particular bio-catalytical processes play an important role already today. Such processes are mostly more selective and specific than conventional chemical processes, leading to higher product quality and purity, and require less energy input and produce less emissions. Very complex organic compounds, especially those with chiral centres, are predominantly produced by microbes already. By 2010, 20 % of all production processes in the chemical industry are estimated to include biotechnological elements (Bachmann, 2002). Also end-products contain enzymes, for example, most washing agents today contain enzymes for effective cleaning at medium temperatures. But not only such fine chemicals, even bulk compounds (like amino acids) and bio-polymers (which could substitute many plastics), made with the help of micro-organisms or their enzymes alone, have been introduced. The main obstacle is the still non-competitive price of the biomass feedstock, in comparison to mineral oil. However, with environment regulations becoming very stringent, and for the looming need to guarantee the safety of chemicals (REACH initiative), bio-based raw materials and cleaner production processes are getting in the focus.

The **paper industry** is increasingly using enzymes for pulp processing and bleaching. The **textile sector** is using bio-based compounds for improved sizing and desizing, cellulases for textile fabrication, elastin-active enzymes for leather treatment, lipases and proteases for cottage purifying, and catalases for bleach removal and peroxidases for de-colouring. Bio-fuels, like bio-ethanol, bio-diesel, biogas and bio-based hydrogen could alleviate the dependence on fossil oil reserves. But the big issue again is price-competitiveness. In **mining**, sometimes micro-organisms are used to extract the ore. For **metal processing**, enzymes help in surface polishing and rust removal.

The **defence industry** is exploring biotechnologies as well, but material on this issue is normally not being published. The US Army has begun last year to spend 50 million US$ over five years to three universities to develop military products using biotechnology (Nature, 2003).

The **cosmetics sector** has been broadening its portfolio with bio-active components that are supposed to affect directly skin cells. Already, enzymes that are claimed to repair DNA damage of skin cells have been added to beauty creams.

All manufacturing industries deal with the problem of **waste production**. Biotechnology is successfully been used for breaking down toxic residues in air, water and soil. Bioremediation offers unique means for degradation of toxins by bacteria or plants. Ideally, waste production can be minimized by a biotechnological upstream process already. Often, the by-products or residues can be transformed into valuable side-products or become re-introduced in the production cycle. **Grey biotechnology** refers to this environmental biotechnology.

The so called blue (marine) biotechnology is still a niche research subject and has not been much commercially exploited yet, but the marine biodiversity will reveal many interesting applications. New pharmaceutically active substances from marine organisms and improved fishery productivity could be the near outcome.

2.2 The process of adopting biotechnology by established companies

The process of adopting biotechnology by established companies involves various entrepreneurial decisions. According to Ambrose (2003) and Bradley (2003), both managers of established companies in traditional industries, the process starts with the realisation of a need for change. Existing processes in the company need to be assessed and criteria for defining what needs to be changed and expectations of implementing biotechnology are defined. The terminology and the basics of biotechnology need to be understood by all participants in the project to avoid misconceptions and rejection. Case studies may help the implementation and the understanding of the new opportunities. The implementation process can be managed as a project, comprising a team or task force with specific milestones and implementation assessments at various stages of the project. Outside parties may further assist the project participants.

Before implementing standardized biotechnology techniques the following questions need to be considered:

- What actions need to be taken to minimise negative interference with existing business?
- What regulatory documentation has been produced on the process before?
- Is the required human resource skill base in place or can it be recruited?
- Are management resources available to control implementation and ongoing needs?
- Will there be any disruption to production and therefore pressure on existing contracts as to delivery, etc?
- Can future demand be met, both from a production capacity position but also financially?
- What is the impact on capital needs (human and physical) and are the necessary funding lines in place?
- Will any increased on costs or savings be passed on to customers?

After the desired biotechnological process has been characterized, suitable suppliers have to be found. After data and information exchange, a site viewing event and a presentation of the suppliers' solutions follow. Other stakeholders should be consulted, including the company's suppliers and customers, and independent advice be taken, too.

2.2.1 Reasons for adoption

According to an unpublished survey in the UK among established companies (Bio-Wise, 2001), the following reasons motivate established companies to adopt biotechnology:

- Compliance with legislation,

- Waste reduction,
- Lower utility costs,
- Improvement of human health and safety,
- Raw material savings,
- Capacity improvements,
- Sales improvements.

Gaisser et al. (2002) present another survey among companies that implemented biotechnological processes. According to these authors 70 % of the companies stated that reduced environmental burden was important for biotechnology adoption, 64 % stated reduced process costs and 22 % referred to improved product quality as decisive factors.

2.2.2 Barriers for adoption

From the technological perspective biotechnology has to compete with established technologies such as the application of the chemical synthesis and catalysis or mechanical treatments. Concerning bio-fuels as an alternative source of energy, biotechnology competes with other energy resources like fossil fuels, tomorrow's fission technology, nuclear, solar, wind, geo-thermal, water and tidal power. This competition with other technologies gives rise to a number of obstacles for adoption.

From the companies' perspective there is a large number of barriers for the adoption of biotechnology. The Bio-Wise promotion programme in the UK has explored some typical barriers in established industries (Mercer, 2003): in many cases technological difficulties in implementing biotechnology were experienced; the belief in the possibilities of the technology was not strong enough; the companies had no awareness about the potential applications; the financing of the process investment was not secured; and finally the regulations were perceived as a barrier.

We will elaborate on these aspects in more detail in this section.

Awareness

In first place, the company needs to become aware of the relevant benefits of biotechnology adoption. But even if a company would be aware of potential advantages of biotechnology, it might not want to adopt biotechnology due to its specific market position. For example, if the company held a quasi-monopoly in a certain market, there would be no short-term incentive for adoption.

Costs

If no transparent cost-benefit calculations are available, it is not easy to convince the potential users of biotechnology's possibilities. Managers usually ask for quantifiable impact as outcome of their actions. This is easier to deliver for standardized processes, but not for totally novel technologies, or those applications that involve intensive research and development activities. Even if reference projects do exist, this still does not guarantee successful transfer into the respective company. Technologies which are profitable on average do not have to be so for each individual firm (Nijkamp et al. 1999). If bio-based bulk chemicals and bio-fuels are concerned, the consistent usage of these renewable materials is very limited today - oil-based equivalents are simply cheaper in most cases.

The risk of imitation

If the established company is using a unique technology that is secured against imitation, it may not want to encourage the diffusion process. Further more, if the implementation of the new technology is expected to be publicly promoted among all competitors, the firm may not want to invest, as it may not able to capture and protect the advantages of the innovation (Nijkamp et al. 1999). In this case, the industry might hold still and wait for the first mover to take the risk of investment and to prove or disapprove the new technology.

Acceptance

New technologies, taken up from external sources, might as well experience in-house denial and rejection of the employees: the so-called not-invented-here syndrome explains such self-marring behaviours (Katz and Allen, 1982).

Demand

Inventions may fail under market conditions. Therefore, the company's suppliers and customers need to be consulted, if the adoption implicates influences on their activities as well.

Implementation competence

Biotechnology is knowledge intense and needs a lot of illustration. The technology holds a lot of imponderability, as living organisms and fragile parts thereof are being used. Thus, for almost all biotechnological processes, an optimization strategy is needed, before an implementation can be considered as being successful. Various factors influence an optimization of the process, and biological systems are too often regarded from a technician's mechanistically point of view. Biotechnological processes are not easily to be scaled up, and laboratory work is far away from industrial dimensions. Skilled workforce is necessary to implement such technologies. Consequently, an appropriate knowledge base must exist or be developed in-house.

The handling of organisms and enzymes is a special challenge. In case the biological components had been optimized by genetic engineering, they might need specially contained environments to prevent deliberate release into the environment. Bacterial and eukaryotic cultures need to be checked regularly for their stability and viability. Phages or virus, and other contaminations pose constant threats. The culture conditions for cells and the reaction milieu of enzymes might not be easily integrated into existing production chains and would need adapted apparatus.

3. Policy approaches to support biotechnology adoption

The benchmarking concept for biotechnology policies developed during the first part of this project identifies four broad sub-areas of the biotechnology innovation system for potential policy intervention:

(1) The development of the knowledge base and human resources,

(2) Knowledge transmission and application,

(3) The market,

(4) The industry.

The adoption of biotechnology for new industrial applications has been included as a key aspect of the sub-area "knowledge transmission and application". Fiscal measures and demand stimulation have been identified as the main policy instruments to stimulate this area of the innovation system. The stimulation of demand for biotechnology involves measures supporting awareness for the possibilities of biotechnology and the access and accumulation of the necessary skills and capabilities by potential adopters. Additionally, regulatory framework conditions can influence the technology adoption process.

Figure 1 sketches the main policy goals in the process of promoting biotechnology adoption and the types of policy initiatives that can help to reach these goals. The first policy goal in the context of adoption is the raising awareness of industry stakeholders of the technological possibilities biotechnology offers. Next we distinguish between public initiatives that support the adoption of biotechnology for novel applications or for standardised processes. For the first type of adoption companies require research and development capabilities in biotechnology. Public promotion programmes can either support the process of accessing these capabilities in collaborative arrangements or encourage the company in the process of building up in-house capabilities. The adoption of standardized processes that are ready to be integrated in existing production lines requires different promotion schemes. Firms engaged in this type of adoption processes can be supported through the consulting services of technology experts that accompany the adoption process in the firm. An additional scheme is the establishment of technology market places as matching platforms for technology problems (from the potential biotechnology adopters) and technology solutions (from developers of standardized biotechnology applications).

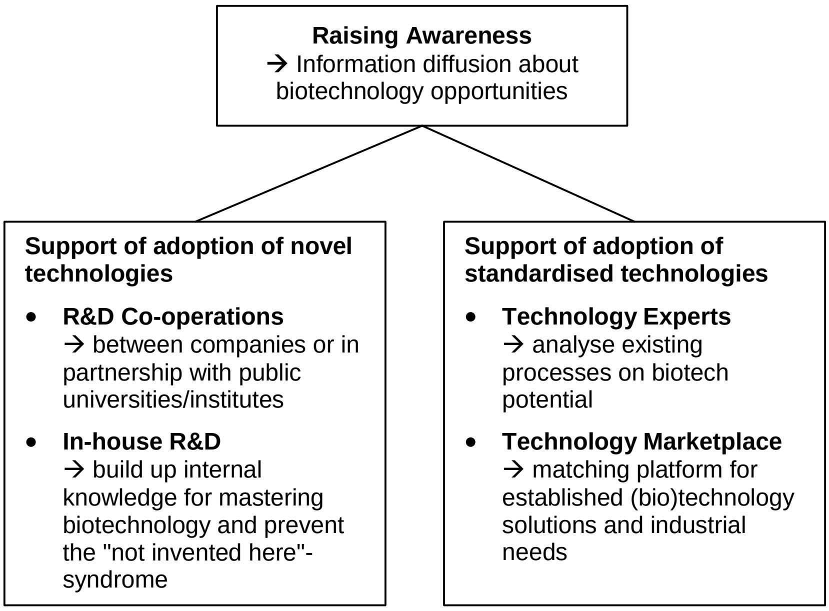

Figure 1 Policy goals and public initiatives for supporting biotechnology adoption

3.1 Measures to raise awareness of biotechnology

Facts, figures and case studies on overall cost and time savings, quality improvement, image impact and the prospect of new markets can contribute to improve company awareness of biotechnology. Such information on opportunities of biotechnology can be complemented by information on threats of sticking to conventional technologies. As an indirect way of raising awareness consumers could be made aware of environmental benefits of biotechnological processes, thus generating a demand for sustainable products.

Cross-disciplinary knowledge and a deeper understanding of biotechnology need to be addressed in promotion schemes to support awareness. Conferences and expositions are suitable tools to disseminate information. There are already many partnering events in place to support awareness of biotechnology, but still few meetings where industrial biotechnology is presented to a non-expert audience.

In the following, examples of measures aiming at raising the awareness of biotechnology potentials at a European and a national level are presented.

Examples

European level

- BioMatNet[38] disseminates results concerning the integrated production and exploitation of biological materials for non-food uses. Over 800 projects from EC Framework Programmes are documented for potential users. The main thematic programmes covered are ÉCLAIR, AIR and FAIR. The data is available online, as well as published on CD.
- Technology platforms aim at bringing together stakeholders from research, industry and policy for information exchange and the set-up of new supporting schemes. The technology platform "Plants for the Future 2025" aims at exploring the development and legal coverage of novel agricultural, food, energy and biomaterials products.
- Regarding other biotechnologies the platform "Sustainable Chemistry" focuses on industrial biotechnology, materials technology, and reaction and process design. The organisations Cefic (representing the chemical industry) and EuropaBio (representing the biotechnology industry) launched this initiative July 2004.
- EUREKA organises the Partnering Event "White Biotech 2004" during the "BIOnale" conference in November 2004 in the Netherlands. Research institutes and companies are the target group of this match making event so as to enable them to encounter, discuss and develop new business opportunities and cooperative R&D projects in the fields of white biotechnology.

UK

- The conference ENABLE II 2004, in association with the British Industry Association, detailed how biotechnology can help companies to meet future legislation and become more competitive.
- The two-day conference "Promoting Biocatalysis: New Developments and Future Prospects" (2004) presented opportunities for the chemical, pharmaceutical, food and textile sectors; it was organized by the Pro-Bio Faraday initiative.

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38 http://www.biomatnet.org/

Germany

- The International Congress on Biocatalysis 2004 was a forum for the exchange of information, targeted at participants from both the academic and industrial sectors.

3.2 Measures to promote the adoption of standardized biotechnology processes

Mainly two types of measures for supporting the adoption of standardised biotechnologies could be identified: financial support for technology experts and so-called technology market places.

Technology experts, also referred to as technology attachés, start their advice with a careful analysis of production processes under consideration at a firm's level. Based on this analysis they elaborate proposals where and how standardized biotechnology processes that are already on the market can be implemented. This external consulting is useful for a technology transfer focussed on the current needs of a company where the expected impact would set in very quickly. The consultant's proficiency and expertise are both key success factors and difficult to assess.

Technology marketplaces are (internet) portals, on which marketable inventions and conceptual formulations for specific technology needs from industry can match.

In the following, some examples of these instruments are presented.

Examples

Germany

- The promotion programme "innovation management" of the BMWA (Federal Ministry of Economics and Labour) offers small companies in Eastern Germany support for an external management to conduct the implementation of innovative processes and products, without a restriction to the type of technology or industry branch.
- The State of Baden-Württemberg has introduced the programme PIUS-BT, which aims at the integration of biotechnology in production industries for environmental protection. An international congress on biotechnology was organized in 2000, where the actual state-of-the-art concerning the implementation of biotechnology into the chemical industry, food processing industry, textile and paper industry was presented. In 2002, a study was supported giving an overview of the stakeholders in the state of Baden-Württemberg, who are developing and implementing environmentally friendly biotechnology, both actual and potential cases (Gaisser et al. 2002). The new programme PIUS-BT for 2004 and 2005 supports internships and diploma theses of students in 10 selected non-biotechnology companies from

varied branches in the State. The university students shall analyse the companies' production processes and examine the benefits of integrating biotechnological processes. The results will be published and presented at local chambers of commerce and industry for information flow on biotechnology implementation. Explicitly, other companies should be encouraged to copy the analysed implementations.

UK

- The Faraday Partnerships are in total 24 initiatives funded by the Government and the Research Councils to improve contacts between industry and academia. The Pro-Bio Partnership aims at the field of bio-catalysis for manufacturing. There are some main centres for research within Pro-Bio, that carry out the academic research parts. The target is to link academia and industry to exploit UK’s bio-catalysis research. Companies interested must become members of Pro-Bio. In turn they can expect technical and financial advice and training. The initiative finances so-called "Technology Translators" (a form of "technology experts"), who visit participating companies. The company can inform the translators of their needs and ideas, which can be published on the Pro-Bio web site. The information is used by the translators to match the company with potential suppliers and partners for the implementation of biotechnological processes, furthermore, the current trends and findings from academic research are continuously scanned for the specific focus.

3.3 Measures to promote the adoption of novel (non-standardized) biotechnology applications

A prerequisite for the adoption of novel and non-standardised biotechnologies by established industries is the adaptation and tailoring of the respective technologies to the industrial processes under consideration. For that purpose additional R&D is necessary at the company level. Depending on the nature and size and the confidentiality of the respective project and not least on the already existing knowledge base at the firm level, such R&D activities can be done in cooperation with external partners or alone.

Research and development in a co-operation with external partners, i. e. public institutes/universities or biotechnology Small and Medium Enterprises (SMEs), is a common way for implementing tailored and novel biotechnology processes. There are both **specific biotechnology** R&D programmes and **generic** technology R&D programmes.

In-house R&D projects without external partners can be designed as **demonstrator projects**, which aim at developing prototypes of biotechnology processes providing a proof of concept and thereby demonstrating the technology's capabilities, economic and environmental benefits.

Examples

European level

- Research and development support for SMEs is offered by EUREKA, a European network to promote innovation in market-oriented collaborative projects by involving industry, research institutes and universities across Europe. The anticipated individual outcome is innovative products, processes and services. Since 1985, more than 1000 projects have been finished and over 700 are ongoing, with a total volume of 20 billion € invested.
- The CRAFT programme addresses the needs of SMEs through "co-operative research and collective research". SMEs are supported that have the capacity to innovate but not sufficient in-house research capabilities. The publications of 159 out of the 884 projects in total (1998-2002) are publicly available and are a valuable information source[39]. Other companies can tap on these case studies on e. g. bio-plastics, food processing, pharmaceutical, agronomical and environmental applications of biotechnology. The intellectual property rights (IPRs) are explicitly regulated: IPRs arising from the projects funded belong exclusively to the SME participants. The budget is about 75 million € in 2004.

Sweden

- The Swedish Agency for Innovation Systems (VINNOVA) aims at stimulating multi-disciplinary, problem-oriented research, where industry partners play an important role. The fields of interest in the programme "Green materials from renewable resources" are composite and fibre technology, enzyme technology and biopolymers. To show how the results of research can be turned into products and processes, demonstrator projects are encouraged. Similarly, VINNOVA promotes problem-oriented research on biotechnological processes with potential implementation in the food industry in the programme "Innovations in foods".

Germany

- The BMBF (Federal Ministry of Education and Research) programme "Sustainable BioProduction" promotes the use of environmentally friendly biotechnology processes in industrial manufacturing. Most projects deal with the production of bulk and fine chemicals. Others topics are biomaterials, food/additives/plants and paper/textile/leather industry. A special project is "BioBeN", which aims at developing a simulation model for the application of biotechnological processes. The

39 http://sme.cordis.lu/experience/case_histories.cfm (source viewed on 9th the Sept. 2004)

software shall deliver a more reliable projection and evaluation on the impact of biotechnology implementation.

- The BMVEL (Federal Ministry of Consumer Protection, Food and Agriculture) programme "Renewable Primary Products" supports both academia and industry in research and development, as well as demonstration projects with a focus on renewable primary products (from natural compounds). New fields of applications shall be opened up in the non-food sector. Information and consultation shall be made available for producers/farmers, processors and users of renewable primary products. The executing organization is FNR (Fachagentur Nachwachsende Rohstoffe, URL: www.fnr.de).
- The BMWA (Federal Ministry of Economic and Labour Affairs) has introduced three relevant programmes: "Pro-INNO", "AIF-ZUTECH" and "InnoNet": Pro-INNO promotes collaborative R&D on new products, techniques and services, without focussing on specific technologies. The joint research can be carried out between companies or companies and public institutes. Furthermore, time limited personal exchange is encouraged. The programme AIF-ZUTECH (9 million € in 2003) aims at corporate change by implementing new technologies in SMEs. Again, co-operative R&D shall lead to technology transfer. Finally, InnoNet's objective is the promotion of innovative networks.; Collaborative R&D is funded for a group of at least four SMEs and two research institutes. The special focus is the combination of interdisciplinary technologies and branches. Example projects are a competence network for biosensors (BioSenZ) and the degradation of heavy metals in staining waste water.

Finland

- Tekes, the National Technology Agency of Finland set up the "NeoBio - Novel Biotechnology" programme in 2001 to advance the development and application of novel biotechnological techniques in production industries, besides the supported emergence of new biotechnology companies.

3.4 The regulatory framework

As an indirect policy approach towards testing the adoption of biotechnology the regulatory framework can create new demand for biotechnological processes by both penalizing non-favoured processes and by fostering the application of biotechnology. However, in this survey we could not identify specific examples for this policy instrument. Rather, only some principle targets for regulatory approaches could be identified.

Regarding the use of energy resources energy taxes can be steering towards the use of bio-based techniques. In tune with this approach the Royal Belgian Academy

Council of Applied Science recommends to introduce a tax relief for bio-fuels (BACAS, 2004).

Concerning environmental protection, several means of regulation can have an impact on the application of biotechnology. In the agro-business for instance, the application of pesticides is becoming more strictly regulated. For the chemical industry, the European Commission's proposal concerning the registration, evaluation and authorization of chemicals (REACH), can be a tool to restrict the acceptable levels of chemicals in production processes and to promote alternative technologies like bio-catalysis.

4. Bio-Wise

Bio-Wise (implemented in the United Kingdom) is a public initiative supporting the adoption of standardized biotechnological processes in established industries. The overall aim of Bio-Wise has been to increase the competitiveness of established industries (potential biotechnology users) by promoting the application biotechnology and to strengthen the supply industry that provides biotechnology know-how (the biotechnology suppliers). Bio-Wise's predecessor (1994 - 1998) was the "Biotechnology Means Business" programme (BMB), which also aimed at the application of biotechnology for commercial and environmental benefit. The Department of Trade and Industry (DTI) has invested 14.5 million £ in the implementation of Bio-Wise. The programme was directed to companies in different established industries that could implement biotechnology applications in their development and production processes. The programme uses two types of promotion initiatives: awareness and technology demonstration initiatives.

4.1 Bio-Wise initiatives

The information initiatives of Bio-Wise include among other an internet-site (URL: www.biowise.org.uk), a helpline free of charge, regional seminars, workshops, exhibitions, an annual conference and several types of relevant publications (biotechnology reviews, industry-specific guides, an inventory of biotechnology suppliers). The internet-site made all publications available free of charge. Furthermore, new relevant information concerning the use of biotechnology has been regularly distributed among programme participants. The events were free of charge for registered members, and on the annual conference, biotechnology suppliers could obtain free exhibition space.

In the framework of demonstrator projects and case studies the programme participants had to go through the process of implementing biotechnology in their development and production processes. The demonstration initiatives aimed at bringing together biotechnology users with biotechnology suppliers and other relevant actors. Firms that participate in Demonstrator Projects were awarded funding on the basis that the results of the project had to be disseminated to a wider audience at a later date. Twenty one demonstrator projects have been supported, most of them in the chemicals, engineering and textiles manufacturing sectors. Cleaner processes had had special attention. The results are documented and made available publicly on the website. According to Darnbrough (2003) in this process 3 million £ have been co-invested by Bio-Wise while 6.5 million £ have been invested by the participant companies themselves. The distribution of the demonstrator projects classified by Bio-Wise according to the type of applications is as follows:

- Aqueous effluent (37 %)
- Biosensors (24 %)
- New processes (19 %)
- Solid waste (10 %)
- Bioremediation (5 %)
- Biomaterials (5 %)

The Bio-Wise programme ended in 2004. The forthcoming DTI Technology Programme, currently being designed, might include industrial biotechnology and include specific action measures.

4.2. Bio-Wise effectiveness

Drawing on desk research and information publicly available and this section aims at exploring the effectiveness of the BIO-WISE programme.[40]

According to an unpublished survey on the biotechnology users participating in BIO-WISE, the programme has helped companies to reduce costs, to reduce waste, to save feedstock, to facilitate meeting standards, and to improve health and safety during production processes (Bio-Wise 2001). Additionally, according to the survey, 85 % of help seekers said that the advice they received was accurate and impartial. Over 70 % attested that the information was new and practical. It was deduced that most companies now judge industrial biotechnology as being cost-effective and reliable.

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40 On behalf of the Department of Trade and Industry (DTI) an independent evaluation and an impact assessment of the BIO-WISE programme has been carried out by SQW Ltd. and Synovate Ltd (UK). A summary with the main findings can be found at: http://www.biowise.org.uk/detail.asp?type=news&menucode=00100002&id=2424. This section draws to a large extent on the summaries of the strategic evaluation and the impact assessment.

These first results from 2001 are coherent with the main findings of the evaluation and impact assessment surveys carried out by independent consultants on behalf of DTI. The surveys found that BIO-WISE has been able to increase awareness, to promote positive attitudes towards the application of biotechnology among users and to encourage user-businesses to consider and to implement industrial biotechnology solutions.

Our analysis identifies 4 main elements influencing the effectiveness of the Bio-Wise programme in reaching these goals: the internet platform, the broad set of supporting initiatives, the incentives for programme participants to disseminate their knowledge and experience and the focus on supporting networking activities between industry actors.

- The strong internet platform:

  The internet presence of the programme seems to be effective in creating awareness among potential programme participants of the existence of the programme and the broad range of biotechnology applications in established industries. The open-access to relevant electronic information free of charge seems to have strong acceptance among programme participants. Electronic information is diffused both actively by the programme management and by the participating companies who share their experience in the adoption processes with other companies.

- The broad set of supporting initiatives:

  The programme includes a broad set of initiatives (from a telephone help line up to the so called demonstrator project competition). Biotechnology users could use different types of instruments along the adoption process (like the help line, newsletters, regional seminars, and support through biotechnology specialists) and hence cover different needs along the adoption process.

- Incentives for biotechnology users to adopt biotechnology and to disseminate information and experience after the implementation process:

  The main thrust of the programme in the last 3-4 years seemed to be the funding of the Demonstrator Projects, which granted companies with funding for the adoption process under the condition to disseminate the results in the internet platform at a later stage. The impact is hence twofold: firstly, the direct support of biotechnology adoption through project funding and secondly, the increased awareness of the benefits of biotechnology among industry actors.

- The strong industry networking:

  The exchange of knowledge and information and the access of programme participants to networking activities seem to be a focus of the programme. In the framework of regional seminars, the potential biotechnology users had the possibility to meet biotechnology suppliers and technology experts.

According to the impact analysis, the impact of programme has been lower than expected. Regarding potential biotechnology user communities that the programme has reached, the impact assessment report finds that there have been fewer potential users applying biotechnology than expected (no higher than 5-10 % against 20 % which was the original goal).

Recommendations for improvement

To obtain the assessment of the programme from programme participants in 2003 Bio-Wise organised a conference ("Breaking the Technology Barrier: Practical Advice to Assess and Implement Biotechnology") where participants were invited to exchange their experiences in the programme and make suggestions for improvement. While biotechnology users were generally satisfied by the BIO-WISE initiative, suggestions from the participants dealt with the need for support of the participant companies after the actual implementation of the biotechnology has concluded. Support like servicing and trouble-shooting once the technology has been implemented would help the end-user in completing a project successfully. Furthermore, the need for all participating parties to document the project and to give feedback was pointed out. In this respect, for successful adoption, the strong relationship between the technology supplier and end-user seems to be a key factor (Ambrose 2003).

Additionally, the independent evaluation and impact assessment point out the following recommendations:

- Further public investment in this type of initiatives due to the slow rate of adoption;
- To strengthen the awareness raising initiatives and the efforts to disseminate information on successful demonstrator projects;
- To design further demonstrator projects;
- To focus the information about the potential industrial biotechnology applications to the characteristics of the user-side businesses. A number of users felt that the programme was too general. Information should be sector specific (i. e. focus more on the specificities of each sector);
- To improve support to supplier companies. Supplier companies felt the need of more support when the projects involved the development of new technologies and products to meet the needs of the user businesses;
- To improve the networking and communication exchange.

5. Summary and conclusions

An effective approach to promote the development and diffusion of biotechnology is the support of biotechnology adoption by established companies, which might not conduct themselves research and development activities. Applications of biotechnology can be found a large number of industrial sectors – the most important ones are the pharmaceutical sector, the agro-food sector, the chemical sector and the environmental sector. The regulatory framework can support the diffusion of biotechnology in these industries by both penalizing alternative technologies and by creating incentives for the application of biotechnology.

The process of adopting biotechnology by established companies often implies the substitution of traditional technologies by biotechnology applications. This process involves the transformation of established processes within the firms. Under these circumstances companies face different barriers that prevent them from adoption biotechnology. The lack of awareness of the possibilities of biotechnology, the lack of competencies or capabilities in biotechnology and the difficulties in quantifying the adoption costs prevent companies from undertaking technological changes in their production processes.

Accordingly, the case study identifies the increase of companies' awareness of the possibilities of biotechnology and company access to capabilities in biotechnology as key policy goals. Awareness of the possibilities of biotechnology to reduce production costs or to fulfil established environmental legislation may have an influence on the attitude towards the motivation for implementing biotechnology. Accordingly, initiatives to increase awareness among companies in established industries seem of major importance. Regarding the access to capabilities in biotechnology, the case study points out the need of promotion schemes to distinguish between the support of adoption processes involving the application of standardized biotechnological solutions (which are ready to be integrated in existing production lines), and adoption processes involving the development and implementation of novel biotechnological applications (which need to be tailored for each specific case). Development and implementation process of novel applications (some times tailored to the user's needs) require more resources.

The exploration of promotion programmes in Europe has identified a limited number of public initiatives to support the adoption of biotechnology by companies in established industries. In regard to the promotion schemes to increase awareness of biotechnology among industry stakeholders, partnering events, technology platforms, project databases and conferences have been implemented or organised mainly by the

European Commission and policy-making institutions in the UK, the Netherlands and Germany. These public initiatives involved stakeholders from industry and academia.

In Sweden, in Germany, in Finland and in the UK different public initiatives have been designed to support the process of implementing biotechnology in the industrial processes by means of facilitating biotechnology expertise to adopting companies through collaborative arrangements with academia. Another policy approach in these countries has been the direct support for building up biotechnology capabilities within the firms through project grants, the provision of adopting firms with qualified staff or with demonstrator projects.

The case study has chosen the public promotion programme Bio-Wise (from the UK) to try to identify success factors for programme definition and implementation. Bio-Wise has aimed at supporting the adoption of standardized biotechnological processes by companies in established industries. Bio-Wise seems to have reached the policy goals of creating awareness about the opportunities of biotechnology and supporting potential users in the biotechnology adoption process, even though these effects have been lower than expected. For example, compared to the original policy goal of at least 20 % of potential users taking up biotechnology, only about 10 % has done it). Our analysis has identified 4 main elements influencing the results of the Bio-Wise programme: the strong internet presence to raise awareness of biotechnology opportunities, the broad set of supporting initiatives included in the programme, the incentives for programme participants to disseminate their knowledge and experiences and finally the focus on supporting networking activities between industry actors.

The case study confirms the results of previous research about the lack of public programmes directed to promote the adoption of biotechnology by established companies in traditional industries. Most public programmes for the development of biotechnology focus on promoting research and on supporting biotechnology start-ups. Innovation policy in most European countries seems to be disregarding the need of supporting the diffusion of biotechnology in traditional industries through awareness initiatives and direct support in the biotechnology adoption processes.

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