European Biotechnology Innovation Systems (EBIS)

Contribution to workpackage 2 (SOE1-CT98-1117)

Case Studies Germany

Stefan Wörner
Thomas Reiss
Martina Menrad
Klaus Menrad
Fraunhofer Institute Systems and Innovation Research
Breslauer Strasse 48
D – 76139 Karlsruhe

July 2000

List of contents **page**

List of tables **page**

List of figures ....**page**

1. Background to the case studies

1.1 General introduction to characteristics of the country

Size and level of economic development

Germany covers 357,000 km² and is home to 82 million people (OECD 1999) yielding 230 individuals/km² (table 1.1). The number of employed individuals in 1998 reached 39,602,000. In 1998, GDP of Germany amounted to 1,925 billion €, i. e. 23,000 € GDP/capita. It is a highly-developed and industrialised country. Regarding Germany's technological performance, the *Bundesministerium für Bildung und Forschung* (Federal Ministry of Education and Research (BMBF[1]) 1999) reports that half of Germany's industrial production is accounted for by R&D-intensive industries (50.5 %). Compared with other major industrialised countries, in Germany this sector has the greatest importance for the national economy: With a contribution by R&D-intensive industries of 12.2 % to gross value added Germany led ahead of Japan (11.5 %), the USA (8.5 %) and the UK (8.0 %); 12.8 % of the total labour force in this country worked in research-intensive industries; in the USA it was 5.9 %, in Japan 9.3 % and in the UK 8.2 % (1993 to 1995)[2].

The development of the contribution to net output shows that in the mid-1990s the research-intensive industries again took the lead in the growth process. This also demonstrates that high technologies - with a contribution of 11.5 % to industrial output - enjoyed the strongest growth. In 1996, high-tech exports rose by 13 % and advanced technology exports by 7.5 %.

Areas of economic strengths and weaknesses

Traditionally, Germany emphasises the advanced technologies in its R&D efforts by specialising in the sectors of automotive, mechanical engineering, electro-technology and chemical industry. In the recent years this emphasis slightly moved to the high technologies like office machines/IT, pharmaceutical industry, air and

---

1 The BMBF has been renamed several times since 1970. This is the new official name, given to the BMBF by the new government in October 1998.

2 The research-intensive sector of an economy consists of "high technologies", i. e. goods whose R&D expenditure accounts for more than 8.5 % of turnover, and "advanced technologies", i. e. goods whose R&D expenditure accounts for 3.5 % to 8.5 % of turnover (ZEW et al. 1999).

space travel and instruments (ZEW et al. 1999). Between 1994 and 1998, investment in high-tech areas and in the automotive sector grew most rapidly in Germany. About 80 % of total additional capital expenditure incurred (or planned) by the business enterprise sector between 1994 and 1998 was accounted for by research-intensive industries.

It has been estimated by the BMBF (1999) that in 1997 investment in innovation by the business enterprise sector would be up 6 % on 1996. Hence this expenditure which apart from R&D investment also includes product design costs, patent fees and the cost of continuing education associated with innovations, rose much faster than industry's R&D expenditure (+3.5 %).

The number of "triad patents" relevant for the world market and originating from industrialised countries is again on the rise[3]. For the first time since 1994/95, Germany has resumed its leadership in triad patents (number of triad patents related to labour force). Germany's leading position in Europe is unchallenged. The number of triad patents in France and the UK is about half that of Germany. But in those countries, too, the number of patents is clearly rising. Especially the USA has steadily expanded its international patent activities (ZEW et al. 1999).

R&D system

Assouline and Joly (1999) classify the German policy system as pluralistic and fragmented. This refers to a national R&D system which is based on public research institutions, such as university departments and other public institutes, with a multiplicity of policy players. Total gross domestic expenditure on R&D (GERD) amounted to 44,758 million € in 1998 thus representing 2.33 % of GDP (gross domestic product; cf. table 1.1) and 510.6 US-$/capita (1997 in purchasing power parities). Between 1994 and 1998 total GERD increased but the R&D intensity (GERD as percentage of GDP) was decreasing. In 1997, there were 11.4 R&D personnel per 1,000 labour force. In 1995, the ratio of total graduates per 1,000 labour force was 5.9. The German research scene is essentially characterised by three sectors: industry, universities and non-university establishments. Since 1994 German business is performing more than 2/3 of the GERD. The rest of the GERD is shared among the higher education sector (≈ 18 %) and governmental and private non-profit organisations (≈ 15 %). However, industry is only financing around 61 % of the GERD thus profiting from governmental financing of about 36 % of the GERD.

---

3 "Triad patents" are patents which, in addition to the country of origin, are pending in at least two foreign markets in different triad regions.

We use the numbers for the GERD published by the OECD (1999) because it covers the resources spent on performing R&D in Germany (including funds from foreign sources such as the EU or companies based abroad) while R&D expenditure financed by domestic sectors also includes the funds allocated to research performed abroad – for which in 1995 government and industry together spent just under 1.4 billion €. As this proceeding eliminates the risk of double counting, this aggregate is often used for international comparisons.

Table 1.1: National Background

	1994	**1995**	**1996**	**1997**	**1998[C]**
Number of Inhabitants [thousand] [A]	81,422	81,661	81,896	82,053	n.a.
Labour Force [thousand] [A]	39,628	39,507	39,713	39,602	n.a.
GDP [billion €] [A]	1,702	1,760	1,802	1,853	1,925
GDP per Capita	20,903	21,553	22,004	22,583	n.a.
GERD [million €] [A]	39,488	40,657	41,363	42,846	44,758
GERD/GDP [%][A]	2.32	2,31	2,30	2,31	2,33
GERD per Capita [PPP $] [A]	458.2	482.1	486.6	510.6	n.a.
Total R&D personnel per 1,000 labour force [A]	n.a.	11.6	11.4	n.a.	n.a.
Total graduates per 1,000 labour force [A]	n.a.	5.9	n.a.	n.a.	n.a.
Higher education sector [% per GERD] [B]	18,7	18,1	18,1	17,8	17,6
Government and private non-profit sector [% per GERD] [B]	15,0	15,4	15,6	15,2	14,3
Business enterprise sector [% per GERD] [B]	66,3	66,4	66,3	67,0	68,1

Source: [A]OECD 1999; [B]BMBF 1999; [C]estimation OECD 1999

Organisations involved in the S&T system

The ministry which has the main responsibility for research policy, the setting up of specialised priorities, budgets, and long-term programmes on an aggregate level is the BMBF (see above). The direct influence of the BMBF on the R&D performing organisations is, however, less important than in case of the departmental R&D (*Ressortforschung*).

Together with the *Länder*, the federal government supports the two major research organisations, the *Max-Planck-Gesellschaft zur Förderung der Wissenschaften*, Munich (Max Planck Society for the Advancement of the Sciences, MPG) and the *Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung* (Fraunhofer Society for the Support of Applied Research, FhG). The federal government provides 50 % of the basic funding for the MPG and 90 % for that of the FhG[4]. The MPG conducts free basic research in new fields of importance for the future. It sets priority areas for top-level research and performs a complementary function, in particular with regard to university research. The FhG concentrates on applied research and its objective is to transfer the results of research into new and innovative products, processes and services.

Other typical organisations in this system are the so-called *Projektträger* which are responsible for the detailed management of nearly all R&D fields supported by the BMBF. In general, the tasks of these *Projektträger* are (BEO 1997):

- To support the federal government concerning development, analysis and evaluation of research programmes and concepts,
- To implement the decisions of the BMBF,
- To consult the applicants for funds, and to support the preparation of the respective projects,
- To assess proposals, to manage the on-going projects and the diffusion of results by organising workshops, publications etc.

The support organisation the *Deutsche Forschungsgemeinschaft* (German Research Society, DFG) is also funded by the federal government and the federal states. As a self-governing scientific organisation it primarily supports universities in all their disciplines by means of projects and programmes. The federal government's contribution is estimated to 50 % or more (BMBF 1999). Together with the MPG and the FhG, the DFG makes a considerable contribution towards the strengthening and integration of research in Germany and also to international co-operation. Support for the next generation of scientists is also of prime importance.

The 16 major research establishments, which have joined together to form the *Hermann von Helmholtz-Gemeinschaft Deutscher Forschungszentren* (Hermann von Helmholtz Association of German Research Centres, HGF), form an integral part of research capacity in the Federal Republic of Germany. They work on complex technical questions and cross-disciplinary tasks, operate large scientific and technical apparatus and develop systematic solutions. The major research establishments receive 90 % of their funding from the federal government and 10 % from the federal state or states in which they are situated.

Together with the HGF, the MPG and the FhG, the so mentioned 'Blue List' establishments could be described as the fourth pillar of the federal government's and federal states' support for research. In the majority of cases the federal

---

4 It should be worth to mention that basic funding only accounts for 30 % of the total budget of the FhG.

government and the federal states provide half the funding for the establishments on the 'Blue List'. The majority of the former 'Blue List' establishments have joined together to form the *Wissenschaftsgemeinschaft Gottfried Wilhelm Leibnitz* (WGL). The 'Blue List' institutes vary greatly in terms of mandate, size, location and legal form. Together with the research establishments, the federal government and the federal states in which those establishments are situated set the priority areas of research which are of national importance.
The *Arbeitsgemeinschaft industrieller Forschungsvereinigung.* (AiF) (Association of Industrial Research Organisations) is another part of the research scene. The AiF is a commercial umbrella organisation comprising around 107 industrial research organisations. The main responsibility of the AiF is to support joint industrial research. Public funding is used to support projects relating to applied research that takes account of the practical needs of small and medium-sized undertakings (AiF 1997).

With respect to the public sector a typical feature of the German R&D landscape is the division of the political responsibilities between the federal government and the *Länder*. The *Länder* are mainly responsible for the educational sector. In consequence they finance the largest part of the university budgets (74 % of all academic research is financed by the *Länder*). Together with the federal government, the *Länder* deal with the expansion of existing and the building of new universities, including university hospitals. In that respect the basic aim is to adapt the universities to meet national and international requirements as an integral part of the overall system of education and research. That also involves promoting priority areas of research at the universities in that field, having regard to the non-university research establishments. Furthermore, the universities are supported by the federal government in areas that require swift and disproportionate support on account of their particular importance or workload by means of fixed-term special programmes that are agreed with the federal states. Such special programmes are used for both teaching and research purposes. Following reunification particular emphasis was placed on the restructuring of universities and research in the new *Länder*. In addition, the *Länder* support projects in local industry and in the national research centres. Total basic funds allocated to sciences by *Länder* and local governments amount to approximately 17.5 billion € per year (Federal Statistical Office; BMBF 1999, Part I, table I/12). Although none of the *Länder* has a specific biotechnology programme, biotechnology is an area of great importance in the *Länder* (Enzing 1999).

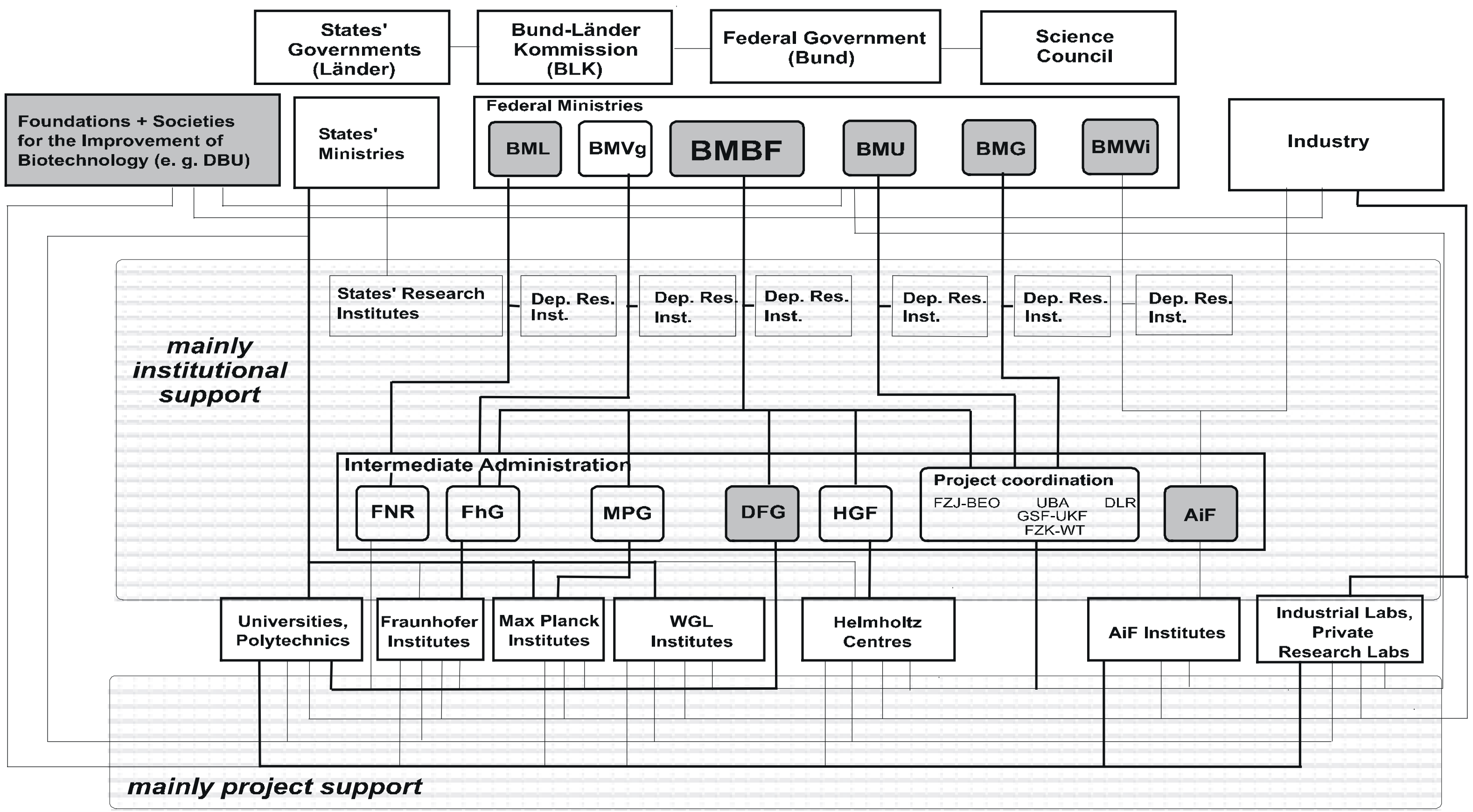
The breadth of the research scene and the fact that a variety of responsibilities are met by the science organisations and research establishments belong to the strengths of the German system of science. Its dynamic further development is one of the central aims of the German research policy. On the side of the German parliament (*Bundestag*) the *Ausschuß für Bildung, Wissenschaft, Forschung, Technologie und Technikfolgenabschätzung des Deutschen Bundestages* ('Committee on Education, Research and Technology Assessment of the German *Bundestag'*) is a key organisation. It drafts decisions of the German *Bundestag* in the field of education and research policy. At the same time the committee acts as an instrument of parliamentary scrutiny of the government's activities in those areas of policy. The corresponding ministry on the side of the federal government is the BMBF. The committee has 38 full members and the same number of deputy members. The composition of the committee in terms of parliamentary parties corresponds to the respective representation of each party in the *Bundestag*.

In addition to its basic function as a specialised committee on its own policy areas, the *Bundestag's* 'Committee on Education, Research and Technology Assessment' is also the controlling body and authority responsible for the *Büro für Technikfolgenabschätzung des Deutschen Bundestages* (TAB) ('Office for Technology Assessment under the auspices of the German Bundestag').

The TAB works exclusively for the German *Bundestag* and is financed by public money. The committee informs the *Bundestag* of the results of the TAB's investigations that the *Bundestag* then refers to the specialised committees for more comprehensive consideration and the drafting of recommended decisions.

A summary of the German R&D system in biotechnology is presented in figure 1.1. The lines between related organisations represent financial flows. Another typical feature of the German R&D system, namely the balance between institutional funding and project funding, is also indicated in this scheme. The line from the *Länder* to the universities comes from the upper part of the diagram because the support is mainly an institutional one. Nevertheless, a small part of the funding of the *Länder* is linked to projects indicated by a thin line coming from below (Gießler and Reiß 1999).

Figure 1.1: Organisations involved in the S&T system



Source: Gießler and Reiß 1999

Public acceptance of biotechnology

In general, the German public discussion about the use of modern biotechnology is still characterised by a rather polarised debate between the supporters and opponents. On the one hand there are euphoric estimations and expectations by the German government and some representatives of science and industry, on the other hand there are sceptical and critical viewpoints, especially from consumer organisations, churches, and ecology groups. However, there is no general scepticism. While the use of genetic engineering is mostly accepted in the medical areas there is still a strong opposition in the German population against the use of this technology in the agro-food sector. This relates in particular to gene transfer among animals and to the application of genetic engineering in food processing (Hampel et al. 1997). In contrast, the use of this technology in plant production meets less opposition especially when resistance mechanisms are concerned (Menrad et al. 1999).

According to the Eurobarometer-survey carried out on behalf of the Commission in the EU no significant change can be registered in the attitude of the German population regarding the use of modern biotechnology since the beginning of the 90s. In all three surveys carried out up to now only around 40 % of the Germans expect clear benefits from biotechnology compared to an EU average of about 50 % to 55 % (European Commission 1997). In contrast, the personal attitude concerning the use of genetic engineering takes the form of an U-relationship since 1990. After a noticeable slump between 1991 and 1993, the percentage of optimists rose again between 1993 and 1996 but still reaching only 32 % agreement in Germany compared to an EU average of 43 % (European Commission 1997). According to Menrad et al. (1999), it can be concluded that there is still a lot of scepticism and hesitation among the German population especially concerning the use of genetic engineering approaches in agriculture and food processing. At least for this application area the "positive development" of biotechnology/genetic engineering which has been announced by the German government has not yet reached the average citizen in Germany. Qualitative indicators in this context are the on-going resistance of different organisations against field trials with genetically modified plants (Mühlenberg 1997) as well as the intensive public debate coming up after the cloning of "Dolly" in the year 1997.

1.2 General Government Policy for Biotechnology

General government policy for biotechnology since 1970

Since the beginning of the 70s, the German federal government supports RTD in biotechnology. In 1970, an advisory group of experts from academic and industrial research was set up by DECHEMA (*Deutsche Gesellschaft für Chemisches Apparatewesen, Chemische Technik und Biotechnologie e.V.*), an association promoting chemical technology and biotechnology. The first step in forming a national programme for biotechnology in West Germany was that the BMBF instructed this committee to elaborate a study on biotechnology of which the first edition was launched in 1974. Since the 80s biotechnology became a strongly growing area of promotion. In 1985, the federal government passed the first research promotion programme called 'Applied Biology and Biotechnology'. This programme built up the basis for the development of an efficient research infrastructure.

In the 90s a growing political awareness of the significance of 'crucial technologies' for the 21st century emerged. In 1990 the federal government passed the programme 'Biotechnology 2000' continuing the programme of 1985. In 1995, chancellor Kohl called the 'Research, Technology and Innovation Council', that (still) consults the government regarding the development and importance of biosciences among others. At present also within technology foresight studies initiated by the BMBF, biotechnology plays an important role in Germany, being considered as one of the 'key technologies'.

A German peculiarity influencing R&D policy is the reunification of the two German republics to an enlarged Federal Republic of Germany composed of 16 *Länder*. The increasing economic constraints and the growing problems on the job market, coming up since the reunification also called for new strategies in R&D policies. Biotechnology together with multimedia and other crucial technologies were considered to bear the potential for opening up new perspectives for the future (Gießler and Reiß 1999).

Policies for public sector research

At present German science and technology policy considers biotechnology as an area of highest priority both on federal and on *Länder* level. General policy goals are to promote broad basic research as well as high level research, to support research efforts in the areas of environment, health, nutrition, energy and raw materials supplies, to improve the research infrastructure (particularly the framework conditions for research and development in industry), to foster investigations on safety and ethical issues, and to strengthen technology transfer and commercialisation, e. g. by supporting SMEs.

The BMBF funds biotechnology R&D through three different programmes, both specific biotechnology programmes and general programmes. Two of them are relevant for the sectors analysed in this study and will thus be described subsequently. The most important programme is 'Biotechnology 2000'. It aims at both a stronger commercialisation of the scientific knowledge, in other words, at the leap from invention to innovation and extending the scientific basis. According to the BMBF (1999) its purpose is "to ensure that also in future Germany will be among the leading countries in this key technology". Programme activities centre on methods and processes which help to protect human health and the environment. Due to the increasing focus on commercialisation, projects headed by industry and raising private co-financing capital have been given priority. The programme was restructured to increase transparency and improve control mechanisms. The various programme priorities are now much more intermeshed and also linked with other funding programmes, e. g. for health research and production engineering/information technology. The major biotechnology fields of interest cover: biomethods (including the basic methods of biotechnology, methods to replace animal experiments, as well as biological safety research), biomatters (including bioinformatics, determination of biological structures, as well as glycobiotechnology), biosystems (including environmental biotechnology, biological systems, and neurobiology) and bioproduction (including catalysis, plant breeding, biological plant protection, and cell factories) (ISB 1998). However, these areas are structured in a very flexible way, i. e. the definition of core research areas mainly depends on trends in the biotechnology R&D scene. Additionally, besides the promotion of projects within these areas every highly innovative project can be funded, i. e. this programme includes both top-down and bottom-up approaches. (Gießler and Reiß 1999) (cf. chapters 2.1, 3.1 and 4.1).

The 'Biotechnology 2000' programme has since 1991 built up the framework for the whole German biotechnology policy. The instruments applied within this programme include project funding, institutional support and structural measures like the 'BioRegio competition' (see below) and the programme 'BioFuture'. This programme was announced by the BMBF in 1998 with the goal to promote and nurture young bioscientists. In particular, the establishment of own research groups is supported in order to strengthen basic research and to open up new perspectives for highly qualified young scientists in Germany. Up to 50 research groups will be supported over five years with a total budget of approximately 75 million €. Like the 'BioRegio' funds the 'BioFuture' budget is also part of 'Biotechnology 2000' programme (Gießler and Reiß 1999).

Four ministries are involved in the programme: those of Education and Research (BMBF), Food, Agriculture and Forestry (BML; financing R&D in the field of renewable raw materials), Economics and Technology (BMWi) and Health (BMG). The biotechnology division of the BMBF is responsible for the implementation of the programme (Enzing 1999). The *Projektträger* Biology, Energy and Ecology (BEO) located at the Research Centre Jülich (FZJ) is responsible for the intermediate R&D management of 'Biotechnology 2000' (Gießler and Reiß 1999).

The BioRegio competition was initiated in 1995 by the federal government and aimed at regional technology transfer and network building. This competition provides significant finance to the regions that developed the most convincing concepts for commercialising biotechnology (Senker 1999). The efforts are strongly supported by the regional governments, incl. supplementary activities, thus emphasising the importance of the regional level with respect to R&D funding (see below for further information).

A second general federal technology programme covering biotechnological fields is '*Gesundheitsforschung 2000*' ('Health Research 2000'). This programme is under the responsibility of both the BMBF and the BMG. The BMBF is in charge of the financing side. The *Projektträger* DLR functions as an intermediate management organisation.

Political tasks and central aims of 'Health Research 2000' are on the one hand to promote health and to fight against diseases, including health prevention and provision, clinical research and research related to the health care system in general. An additional goal is to improve the structure of health research including networks of basic research and clinical research, long-term establishment of new research structures, as well as important fields of public-health policy.

Health research is mostly done by the German universities. Supplementary, some HGF-, MPG-, FhG-, and WGL-institutes as well as departmental research organisations are working on medical relevant questions. In addition to public research, the pharmaceutical and the medical technology industry are important players in health-related research. However, this is mainly done independently from public research programmes.

Technology transfer

Besides the BioRegio competition (see above) the federal government also applied other measures to promote technology transfer. Between 1991 and 1996 an indirect-specific promotion measure within 'Biotechnology 2000' aimed at facilitating the adoption of biotechnology by small and medium-sized enterprises. Other non-biotechnology specific measures include the foundation of *Agenturen für Technologietransfer und Innovationsförderung* (Agencies for Technology Transfer and Innovation Promotion) (ATI) and Technology Transfer Centres (TTZ) with different specification (e. g. concentration on specific industrial sectors or specific technologies) (BMBF 1996). A specific institutional response to the growing demand for increased technology transfer from university to industry are the so-called *An-Institute* ('institutes at the university'). These institutes are legally defined as independent entities and they rely on industry funding for roughly one third of their total research budget (Schmoch et al. 1997).

Another measure to enhance technology transfer in a certain area has been established in 1997 under the 'Human Genome Research Project'. This model aims at the systematic and comprehensive patenting of research results (cf. chapter 2.1 for further details).

Industrial policy

The most important actor for industrial policy in Germany usually is the BMWi. The BMWi is also involved in programmes to encourage firms to adopt new technologies and to raise industrial awareness for biotechnology (among others). The BMWi is particularly responsible for several programmes aiming at the support of the new *Länder*. These are mostly directed to small and medium-sized firms and include, for example, the support of R&D co-operations or the building up of R&D personnel. However, all these programmes are general and have no biotechnology focus.

The R&D expenses of the BMWi between 1994 and 1998 (estimated) were decreasing from 538 million € to 440 million € (BMBF 1999). Additionally, the BMWi promotes application-orientated research by using the AiF (cf. 1.1) as an intermediate management organisation. The rationale behind this structure is the interest of industry to obtain public promotion for collaborative research efforts and the federal interest in efficiently channelling public funds through one mediating umbrella organisation to the various industrial research associations. The promotion of co-operative research is financed by public funding and contributions of the AiF members. In 1997, the AiF comprised 23 research associations covering biotechnology in the industry sectors food, textile, paper, wood, leather and chemistry[5]. In 1994, public funding for research in biotechnology relevant research associations amounted to around 31.2 million € - approximately 35 % of total public funding by AiF (Gießler and Reiß 1999).

Additionally, the German government provides direct project funding for biotechnology research in industry (collaborative research), but usually provides less than 50 % of the project costs (cf. chapter 1.3 for the amount of money spent for this purpose). Industry may also be involved in co-funding the Gene Centres,

5 All in all, 109 research associations representing around 50,000 companies (mainly SMEs) were joined within the AiF.

which are often based on collaboration between centres of expertise in universities and Max-Planck-Institutes, receiving money from one or a group of companies.

In general, industry does significantly participate in biotechnology policy development as Germany is home to large multinational companies (MNCs) in the pharmaceutical, agro-chemical and food and drink sectors (Enzing et al. 1999). Due to their research activity and to their influence on the policy-making process, federal and regional governments take advice from industry on the design of research programmes.

Table 1.2: Industrial Policy

Instrument	**Date**	**Target Group**	**Aim**	**Means**	**Budget**
AiF Funding	1994	SMEs	Support of co-operative research	Financial support	31.2 million €
Direct project funding	permanent	Any biotech company	Support collaborative research	Providing less than 50% of the project cost	
BioRegio	1995-2001	industry, science, policy, administration, and financing organisations	promote and accelerate the transfer of biotechnological know-how into products, processes, and services	Competition; project funding	555 million €

Policy to promote public acceptance of biotechnology

The federal government, mainly through the BMBF, tried to overcome still existing fears by campaigns to increase general knowledge about biotechnology. Examples for this are

- The programme 'school-ethics-technology' (SET), which was designed to enable pupils to consciously cope with new technologies in general and with modern biotechnology in particular. It is funded by the BMBF and the (state) government of Baden-Württemberg and was set up at a number of schools (primary and secondary) in Heidelberg.

- The 'BioMobil', which is funded by the BMBF and the (state) government of Bavaria. It is a mobile point of information to inform the population about the chances and risks of biotechnology.
- The 'information secretariat on biotechnology', which was established in 1996 and is funded by the BMBF. Its aim is to provide information to all questions which are connected with biotechnology, including evaluation of economic, scientific, technological and societal developments.
- A number of ELSA studies, which were initiated by the TAB in the past. The TAB is still active in specific biotechnology fields. In addition there has been an initiative by the BMBF to support a 'Centre of Competence for Bioethics' (Enzing 1999b).
- A number of actions at schools or museums, e. g. experiment-shows, workshops and exhibitions.

Rationale behind these activities seems to be the assumption that acceptance might rise depending on the level of information among the public. According to our experience, this rationale still waits for a proof. Hence, the federal government recognised the lack in public acceptance of biotechnology but did only come up with a number of separate measures rather than a focused strategy.

Policy to encourage interaction between the various networks

A structural measure to encourage interaction between the public-private networks is supported within the 'Biotechnology 2000' scheme. In this context, the already mentioned 'BioRegio competition' is the most important instrument. The BioRegio contest was launched in October 1995 with the goal to promote and accelerate the transfer of biotechnological know-how into products, processes, and services. This goal should be achieved by concerted efforts in different German regions. In particular the systematic co-operation between industry, science, policy, administration, and financing organisations should be stimulated. Each of the 17 regions participating in the contest was awarded 50,000 € to prepare their proposals. The competition was judged by a panel of experts from industry, science, and business. Finally, three winner regions – Rheinland (Cologne, Düsseldorf, Wuppertal, Aachen), the Rhein-Neckar triangle (Heidelberg, Ludwigshafen, Mannheim) and Munich were selected. An additional price was granted to the region Jena. The three winning regions will receive additional project funding combined about 75 million € over five years starting from 1997. These funds are entirely provided within the 'Biotechnology 2000' budget – there are no additional 'BioRegio' funds.

1.3 The Science Base

Some methodological limitations should be kept in mind when reading this chapter: the numbers presented are based on official reports (e. g. by BMBF) and on published studies. However, it can not be claimed that the 'correct' numbers are necessarily found as official figures for biotechnology area funding have not been available. We therefore had to give estimates for such figures, which represent a range of upper and lower boundaries.

Amount of funds available for biotechnology research and donators

Due to the division of the political responsibility between the federal government and the *Länder*, the German R&D landscape is rather complex. Both on federal and state level several actors are funding biotechnology to different extents.

On the federal level the most important funding organisation is the BMBF. Since 1994 the BMBF invests around 5.5 billion € for R&D per year. This corresponds to 65 % of the total R&D expenditures of the federal government. Its R&D expenditure on biotechnology rose at a compound annual growth rate of +8.7 % from 46 million € (1981) to 162 million € (1996). Even though the BMBF's total R&D expenditure dropped, the budget figure for the biotech funding area in 1997 was up 13.1 % on 1996. After this substantial increase expenditure for 1998 (government draft) will presumably not rise that steeply (BMBF 1999). In the last 18 years, total federal expenditure on biotechnology (BMBF and other governmental departments) boasted high, above-average compound annual growth rates over all phases (from 1981 to 1996 +9.9 %).

Every year the BMBF and its subordinate agencies allocate more than 500 million € to promoting research and technology in the fields of biosciences and molecular medicine (Gießler and Reiß 1999). This sum also includes the funds spent on pertinent research within the MPG, the DFG, and the FhG which according to Gießler and Reiß (1999) amounted to approximately 227 million €. Around 166 million € were spent for structural funding and about 111 million € for project funding. In 1998, 170 million € were appropriated for the 'Biotechnology 2000' programme alone (including basic funding of institutions, especially the *Gesellschaft für biotechnologische Forschung mbH* (GBF - Biotechnological Research Centre), Braunschweig-Stöckheim, the *Max Delbrück-Zentrum für Molekulare Medizin* (MDC – Max Delbrück Centre for Molecular Medicine), Berlin, and the GSF - *Forschungszentrum für Umwelt und Gesundheit* (GSF - Environmental and Health Research Centre) Neuherberg near Munich, as well as several 'Blue List' institutes such as the *Deutsche Sammlung von Mikroorganismen und Zellkulturen* (DSMZ - German Collection of Micro-organisms and Cell Cultures). This is complemented by activities in other funding areas which in some cases also tackle biotechnology issues, like the health research and development. Since 1993, the BMBF places annually around 276.9 million € at disposal for this area, including around 95.7 million € for project funding (BMFT 1993, BMBF 1996). Unfortunately, a detailed description of biotechnology-related research promotion in this field is not possible (Gießler and Reiß 1999).

In addition to the BMBF, the BML spends more than 50 million € a year to fund research into renewable raw materials, as well as biotechnological research work performed at nine of the ten federal research institutes within its jurisdiction. The research expenses of the BML are estimated at around 261.8 million € in 1997 (Gießler and Reiß 1999). The major part of research on behalf of the BML is done by its own departmental research organisations which support the ministry in scientific problems and decision-making processes. The major goals of the BML are to promote small and medium-sized enterprises, to support technology transfer, and to improve frame conditions like acceptance of gene technology. The departmental research work mainly centres around ecosystems and resources, environmental friendly agriculture and production, as well as food quality and renewable resources. All in all, around 25 % (approximately 65 million €) of the total R&D-budget in 1997 for departmental research can be associated with biotechnology (BML 1998).

Within the programme "Renewable Resources - Concept of the Federal Government to promote Research, Development and Demonstrations 1996-2000" the Federal Government places around 27.7 million € annually at disposal for R&D, including around 6.5 million € for departmental research work of the BML (BMBF 1996). This programme continues a promotion concept passed in 1990. The responsibilities for the implementation of the programme shifted from the BMBF to BML in 1993. Nevertheless, different programmes of the BMBF contribute to the basic knowledge in the field of renewable resources (BML 1996). The *Projektträger Fachagentur Nachwachsende Rohstoffe* (FNR) in Gülzow acts as an intermediate R&D management organisation (Gießler und Reiß 1999). The main actors being funded within this programme are universities and other public research organisations (74 %), whereas the public share contributes between 90 % and 100 % of project costs. 26 % of the biotechnological projects are performed by industrial research institutes, with 50 % public promotion (FNR 1998).

On the state level the respective ministries of economics, of science, and of environment are funding biotechnology research. Besides federal or state ministries a variety of other funding associations and donations exists.

The breakdown of federal R&D expenditure by funding area and funding priority (table 1.2) is based on the federal government's R&D planning system which permits an analysis of expenditure in terms of research themes, irrespective of the financing government department. For the BMBF, expenditure is assigned at project level, for the other ministries at budget item level. The resources appropriated for basic funding of institutions, including the HGF, as well as the funds allocated to government-owned scientific institutions are also assigned to one or several funding areas or priorities, in keeping with the institutions' tasks and according to research themes.

Table 1.3: Federal R&D expenditure by selected funding areas and funding priorities

Federal R&D expenditures by selected funding areas [million €]	**1990**	**1993**	**1996**	**1997 (budget)**	**1998 (govt. draft)**
Biotechnology (funding area K)	139	198	208	235	237
Research and development in the service of health (funding area G)	302	391	390	402	404
R&D in agriculture, forestry and fishery (funding area R)	114	147	131	131	136

Source: BMBF 1999, Overview 4.1

When calculating the total amount spent by federal funds according to table 1.2, the numbers for the 'biotechnology funding area K' represent the lower boundary of federal expenditures on R&D in biotechnology. Additional resources were devoted to biotechnology-related fields in funding areas G and R. However, public offices do not distribute more detailed numbers for each funding area.

Gießler and Reiß (1999) therefore tried to estimate the federal funding of biotechnology in Germany (table 1.3). They used annual figures for 1997 for all funding organisations but BMBF where 1998 data are shown. The authors then calculated total biotech budgets based on the annual figures assuming that these could be considered as average figures for the period 1994 to 1998.

The authors thus estimate the annual amount of total federal funding of biotechnology to around 604 million € in 1997 (Gießler and Reiß 1999, table 1.4). Both policy-directed and non-policy directed public spending amounted to roughly 50% of biotechnology R&D raised through general and specific biotechnology programmes in Germany during 1994 and 1998 (Assouline and Joly 1999). The total corresponds to 1.5 % of the GERD or about 4 % of the GERD financed by government. Considering just the R&D expenditure of the federal government, which were about 8,670 million € in 1997, biotechnology reached a share of approximately 7 % of this budget.

Table 1.4: Summary of federal funding of biotechnology in Germany.

Funding Organisation	Programme/ Receiving Organisation	Total Annual Budget (million €)	Annual biotech budget (million €)	Biotech budget 1994 - 1998 (million €)
BMBF	project funding within Biotechnology 2000		111.0	555.0
	basic funds MPG, DFG, FhG		227.0	1135.0
	structural funds: HGF, WGL		166.0	830.0
BMU	Eco-research plan		0.3	1.3
BML	departmental research organisations	260.0	65.0	325.0
	Renewable Resources	27.7	3.8	19.0
BMWi	AiF-Research	89.0	31.2	156.0
Total			604.3	3021.3

Source: Gießler and Reiß 1999

Funding regime

An important aim of the German biotechnology policy is to foster the co-operation between public and private organisations. The BMBF took several measures to promote networking in biotechnology R&D. Important instruments include the Gene Centres, the *Verbundprojekte* (linked projects), and the *Leitprojekte* (target projects). Between 1982 and 1995 the BMBF funded the foundation of Gene Centres with about 140 million €. In addition, during the same period about double of these funds could be mobilised from other sources including industry, the *Länder*, the MPG, the European Union, and others.

Under the framework of the programme 'Biotechnology 2000' the main part of funded research projects are linked projects. Within these projects co-operative research between industry and universities or other research organisations is funded. Thereby, mainly application-oriented basic research and complex pre-competitive research are supported.

A new network instrument created at the end of 1996 by the BMBF, is the so-called target project. This new approach focuses on interdisciplinary and institutional co-operations between science and industry. Universities, research organisations, and industry collaborate right from the start of research activities related to application. These target projects are top-down approaches, designed as competitions, with a privileged position among the projects funded by the BMBF. Target projects already announced by the BMBF are dealing with molecular medicine and modern processes for food production (BMBF 1997b).

Considering future development in the national biotechnology funding system, the situation in Germany as outlined above might not dramatically change in the near future insofar as the general structure of the funding system in biotechnology is likely to remain the same over the coming years. However, some desired amendments in this system are worth to be mentioned (Enzing 1999). The 'Advisory Board for Research, Technology and Innovation' (1997) suggests

- An improved co-ordination of biotech funding activities through concentration on 'Centres of Excellence', also because of their network function,
- Stimulation of interdisciplinary research, and
- Competition as in the 'BioRegio contest'.

IPR policy

Specific measures to foster commercialisation dealing with intellectual property rights and patenting include the 'patent initiative' of the BMBF in 1996 that aims at improving the patenting of research results. The target of this, so-called INSTI-project ('promotion of innovations by scientific-technical information'), is to place a network of points of information for researchers all over Germany at their disposal. With respect to research organisations, another target of this initiative is to foster information activities about intellectual property rights. Moreover, the BMBF extended the possibilities for receiving funds for patent applications.

Figure 1.2: Structure of German IPR policy (BMBF 1999)

pillar 1	**pillar 2**	**pillar 3**	**pillar 4**
Framework conditions for inventors	**Patent initiative 'research institutions' (public as well as private research institutes)**	**INSTI-project**	**Support for SME-patents**
• Measures on the patenting rules (legal) • Support for inventions • 'Climate for innovations' (rising public awareness for inventions)	Objective: • Increasing patenting consciousness • Increasing patenting exploitation through rising awareness of/at: • University teachers • University administrations • Ministries of the *Länder* • Large-scale-research facilities • Blue-list-institutes	Broad approach for: • Using information on patents and scientific-technical information • Patent search • Advising inventors • Training courses • Integrating patenting in academic education • Network of start places on patent questions	Paying half of external cost for the first patent application of SMEs in the last five years

Additionally, the BMWi supports the development of the 'Patent Information Centres' (PIZ). Latter aims at the improvement of the information level of small and medium-sized enterprises about the status of technical developments (BMBF 1996) (Gießler and Reiß 1999).

The German IPR policy comprises four pillars as shown in figure 1.2. The focal points are to improve the framework conditions for inventors in general (pillar 1), to support the patenting activities of (public and private) research institutions (pillar 2), the INSTI-project described above (pillar 3) and to encourage SMEs to patent their research results (pillar 4).

Patenting situation and rules for academic IPR

Concerning the patenting situation at the universities no general statements can be made. The extend, to which the patenting system is known and used differs from university to university and even from institute to institute. Some universities established own strategies to ensure the identification and commercialisation of research results (e. g. Karlsruhe and Dresden) whereas others joined programmes initiated by the *Länder* (e. g. by Baden-Württemberg, Bavaria, Lower Saxony). However, many universities do not have such policies at all. Hence, initiatives to patent research results at those universities depend on the 'privileged' (by law) local university teachers. Regarding patenting cost at the DPA (German patenting office), the expenses are considered to be 'innovation friendly'. A patent application at the DPA costs 330 – 360 € fee plus 1,500 – 4,000 € patent-lawyer-cost. The annual fee to be paid to the DPA amounts to 1,175 € up to the 10th year after application.

§ 42 Arbeitnehmererfindungsgesetz (ArbNErfG)

The law that controls the rights on inventions made by university teachers is the § 42 ArbNErfG[6]. According to this paragraph, inventions by professors, lecturers and scientific assistants at universities are 'free inventions', i. e. if a patent is issued, the inventor is the proprietor of the patent rather than the (research) organisation (e. g. the university). This rule does not apply for employees of the MPG, the FhG, the HGF and the institutions of the WGL. Hence, there are two possible kinds of inventions at German universities: inventions by individuals belonging to the group of people according to § 42 ArbNErfG (in this case the university can merely acquire the rights on the invention by signing a contract) and inventions by others, e. g. by (non-privileged) scientific employees and other staff, which can be commonly claimed by the university (the employer).

6 Law concerning inventions made by employees.

Two contrary opinions about the § 42 ArbNErfG are prevailing. One group interprets the current legal situation as positively encouraging university teachers to commercialise their inventions because this would have a direct effect on their private income. Besides, it would not be in line with the constitution of the Federal Republic of Germany if § 42 ArbNErfG would be cancelled. The other group considers these reservations as not too much in conflict with the constitution but forwards the suggestion to eliminate § 42. They reason this with mainly two arguments:

- Inventions at public universities are made with public funds and therefore the public (represented by the university) should also have the rights on these inventions,
- The infrastructure at the universities to commercialise inventions made on their campuses could be more efficiently utilised if the universities would be responsible for the application and the administration of all patents derived from inventions made on their campus.

Nevertheless, compared to other European states, the number of patent applications forwarded by German universities (including the privileged persons mentioned above) is above average. However, substantial deficits can be reported regarding commercialisation as the patents from German university research are considerably fewer commercially used compared to both patents from (German) enterprises and American university research (Becher et al. 1996).

Post-graduate courses available in higher education

In the German system, there are no doctorate courses with a limited number of students like in the Anglo-Saxon system. In traditional programmes, German doctoral candidates have no formal admission procedure or organised programme of course requirements. The doctoral research is supervised by the professor who accepts the candidate. Each research institute at university might offer a certain number of jobs to graduate students with the intent to draw up a dissertation. Additionally, there is a number of students who wish to work at a non-university research institute (e. g. one of the FhG or the MPG).

Human capital in biotechnology

To estimate the quantity and breadth of human capital in biotechnology in Germany, we collected numbers provided by the Federal Statistical Office (1999) on students studying biotechnology and related fields at German universities as well as the number of dissertations completed in such subjects. The problem of such an approach is that these are official figures for 'biotechnology' which however represent only a minor fraction of the biotechnology relevant disciplines. Therefore we had to scan all science disciplines covered by the statistics and define which ones are relevant for the three sectors under consideration. The subjects finally taken into account and the corresponding sectors are mentioned in table 1.5.

Table 1.5: Fields of studies related to biotechnology and assignment to the three sectors under consideration

Subject	**Sector**
Medical computer science	Bio-pharmaceuticals
Bio-chemistry	Bio-pharmaceuticals
Pharmaceutics	Bio-pharmaceuticals
Biology	Bio-pharmaceuticals/agro-food
Food chemistry	Agro-food
Veterinary medicine	Agro-food
Agricultural biology	Agro-food
Agricultural science/farming	Agro-food
Brewery/beverage technology	Agro-food
Food technology	Agro-food
Dairy farming	Agro-food
Plant production	Agro-food
Livestock production	Agro-food
Biotechnology	Equipment and supplies
Chemical engineering	Equipment and supplies
Process engineering	Equipment and supplies
Micro system engineering	Equipment and supplies

Numbers on subjects like molecular biology and micro-biology are included in the numbers for biology. On the other hand, 'biology' also includes subjects like systematic botany or animal systematics which are not relevant for our purpose. We therefore tried to estimate the number of students studying biology in relevant fields. We asked deans responsible for biology at nine major universities (Freiburg, Heidelberg, Tübingen, Munich, Frankfurt, Köln, Düsseldorf, Münster, Berlin) to give estimates about the relative distribution of their biology-students in fields 'relevant for biotechnology' and 'not relevant for biotechnology'. With these statements we calculated a mean (54 %) and multiplied it with the total numbers for biology provided by the Federal Statistical Office. Due to the fact that students in biology are likely to have useful qualifications for both the bio-pharmaceuticals and the agro-food sector, the 'relevant number' of biology students was assigned equally to both sectors as it was not feasible to further distinguish their distribution on sub-fields.

We also included the subject of pharmaceutics in our statistics although most of the graduates join the dispensing chemist's. Nevertheless, we found this proceeding appropriate as we intended to estimate the manpower that is potentially relevant for

occupations in biotechnology. This applies for the pharmacists who experienced an education that enables them to do scientific research in biotechnology – irrespective of what their first job will actually be in most cases.
The numbers provided by the Federal Statistical Office include

- Number of students for the semester 1994/1995, 1995/1996, 1996/1997 and 1997/1998 for particular subjects (table 1.5),
- Number of exams passed and doctorates awarded in the years 1996 and 1997 in the above fields (data for years earlier than 1996 as well as for 1998 were not available).

Figure 1.3: Numbers of people occupied in academic training at German universities in fields related to the three sectors in the period of 1994-1998

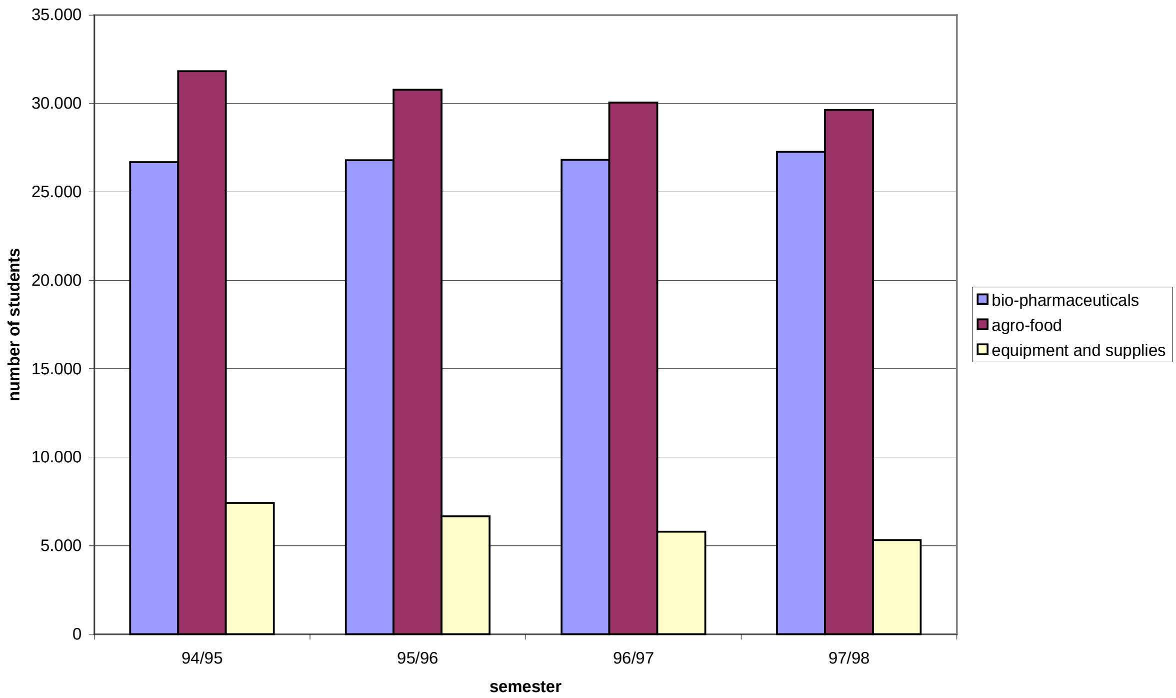


Figure 1.3 shows the number of students occupied in academic training at German universities in fields related to the three sectors in the period of 1994-1998. Accordingly, subjects related to bio-pharmaceuticals and agro-food sciences attract most of the students in the general fields of biotechnology. The equipment and supplies area has a significantly lower share which is further more slightly decreasing over the years. The numbers in agro-food subjects were slightly falling whereas the ones on bio-pharmaceuticals increased a little through 1994-1998.

Table 1.6 provides average numbers of graduates from German universities in subjects related to the three sectors through 1994-1998. The figures confirm the findings discussed above. Nearly the same number of students is graduating in fields related to bio-pharmaceuticals and agro-food whereas the equipment and supplies sector is rather underrepresented. Keeping the two to five years time-lag between completion of studies and the award of a Ph.D. in mind, we might conclude that a significantly lower share of the equipment and supplies graduates aim for a doctorate compared to the students of agro-food areas. The bio-pharmaceutical students are somewhere between.

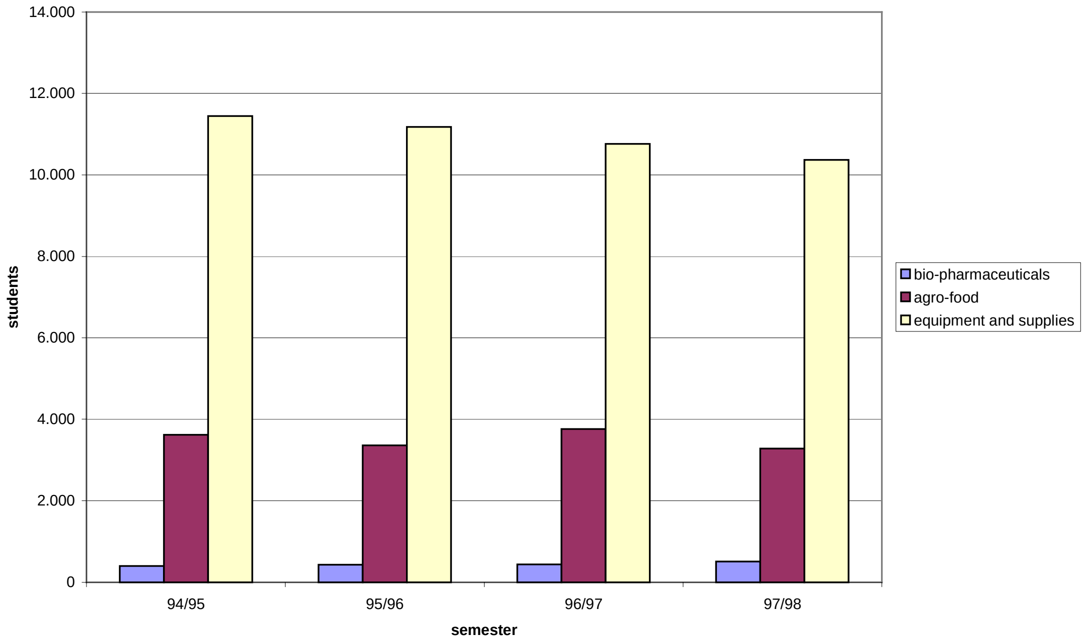
Table 1.6: Average number of awarded doctorates and students graduating in subjects related to the three sectors between 1994 and 1998

	Bio-pharmaceuticals	**Agro-food**	**Equipment and supplies**
Graduates (avg. 1994-1998)	2.944	3.002	914
Doctorates (avg. 1996-1997)	808	1.117	165
doctorates/graduates	27 %	37 %	18 %

The German system of higher education distinguishes between *Universitäten* (universities) and *Fachhochschulen* (universities for applied science). The latter are more practically oriented whereas basic science is usually more emphasised in the former. Figure 1.4 presents the numbers of people occupied in academic training at German *Fachhochschulen* in fields related to the three sectors in the period of 1994-1998. It is striking that the relations between the three sectors turned in favour of the equipment and supplies sector. This still holds true if the number of graduates is concerned. Significantly more people are graduating from German *Fachhochschulen* in subjects like biotechnology, chemical engineering, process engineering and micro system engineering (on average 1.477 in 1996 and 1997) than in agricultural science and farming, food technology and dairy farming (on average 568 between 1996 and 1997) or medical computer science and bio-chemistry (103 on average between 1996 and 1997).

Regarding the question, whether the public education system is training skilled manpower in the area under consideration, a clear statement based on analytical investigations is hardly possible. According to representatives of universities (deans and other staff) it is more important to have a broad basic knowledge (that might be further extended and specialised by a dissertation or training on the job) rather than an education that focuses quite early on a certain subject. Accordingly, biologists and chemists might see themselves in advantage compared to biotechnologists from a German university or *Fachhochschule*. Further more, a particular knowledge in a certain field might not be as valuable as flexibility and the ability to analytically plan and organise its own work (and the work of others) in a new area.

Figure 1.4: Numbers of people occupied in academic training at German *Fachhochschulen* in fields related to the three sectors in the period of 1994-1998



According to a study of the *Institut für angewandte Innovationsforschung* (IAI) (Institute for Applied Innovation Research, Bochum), future prosperity of the young German biotech-industry might be hampered by a lack of competent staff, particularly qualified employees and executives, who are able to transfer complex biotechnological know-how into innovative products and services and maintain their customer-oriented exploitation. This appears to be paradox because of the huge number of 90.000 unemployed (natural) scientists and engineers in Germany. This contradiction – the personnel bottle-neck in spite of sufficient quantitative resources – can be explained by deficits in crucial competencies of the university graduates:

- Lack of cross-skilled know-how, e. g. chemists who do not have basic knowledge in bio(techno)logical matters,
- Deficits in practical experience (in companies or profit organisations) as these qualifications are usually not supported within the German education scheme in subjects like chemistry or biology. The students are not encouraged to undertake placements in companies or do research on subjects strongly related to applications in industry.

According to the authors of the study (Staudt et al. 1999), this gap might even increase in future due to the rising demand for personnel by the growing German biotech industry, particularly in sales departments.
Menrad et al. (1999) also identify problems of biotechnology SMEs to hire qualified and experienced personnel, particularly executives and scientists with a basic knowledge in business administration. Experienced managers from the pharmaceutical industry (domestic or from abroad) usually ask for higher salaries than the young biotechnology companies are able or willing to pay. Besides, stock options are less attractive for the holder in Germany than in the UK or the US due to the unclear legal and tax situation in Germany.

Table 1.7 briefly summarises the results achieved so far in this section.

Table 1.7: Policy for the Science Base

Element	**Indicator**
Organisations involved in funding public sector research	BMBF, BML, BMU, BMWi, other governmental departments
Budget for biotechnology research provided by those organisations	Total annual biotech budget: 604.3 million € (average) Number of special programmes: 5-10
Public organisations involved in performing biotechnology research	Number of institutes (PSR): 48 Number of university departments: several hundred
Specialised life sciences workforce	Number of doctorates awarded 1994-1998: 2,090 R&D personnel in public sector: 12,100[A]
Successful applications of German co-ordinators in EC FP 4	
- Biotech	63
- Biomed	68
- Fair	52
Successful German partners in EC FP 4	
- Biotech	588
- Biomed	711
- Fair	409

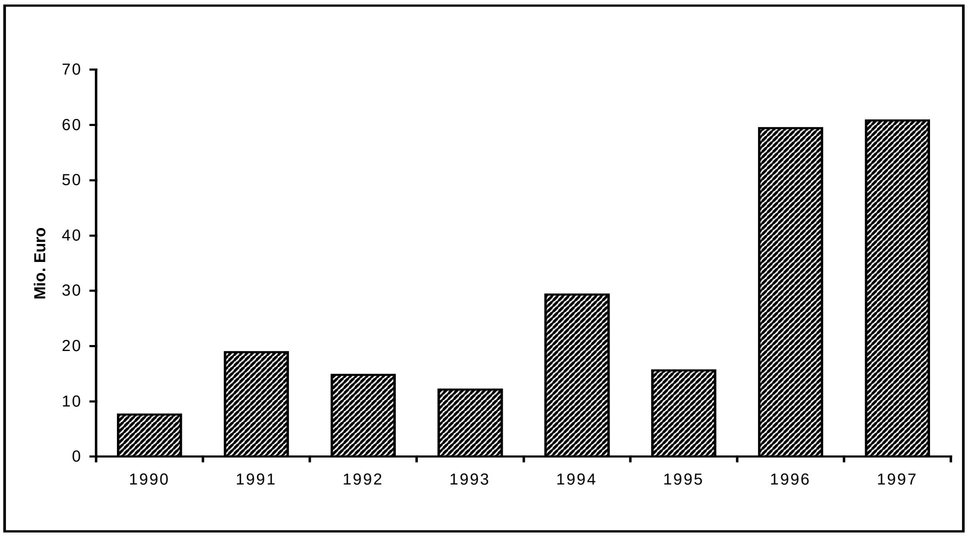
[A]: full time equivalents at universities and PSR organisations; Federal Statistical Office Germany 1995

1.4 Other

Private investment capital

An overall aim of the German biotechnology policy is to mobilise private capital by giving incentives and to reduce the share of public funds for research projects. Important tools in this context are the so-called linked projects (*Verbundprojekte*) and target projects (*Leitprojekte*). The general situation of private investment capital considerably changed during the period under consideration as the lack of (venture) capital turned into an 'abundance of money' seeking for investment (cf. figure 1.5). It is expected that the numbers for 1998 will again double compared to 1997. This is particularly true for the bio-pharmaceuticals sector. Venture capitalists prefer to invest in this sector due to the potential for a high return on investment, especially when an exit via an IPO at the stock exchange is concerned.

Figure 1.5: Development of equity capital newly invested in biotechnology in Germany between 1990 and 1997



Source: EVCA

In the recent years, a number of firms carried out an IPO at the stock exchange. The newly created segment of the *Neuer Markt* in Frankfurt was rather successful which also encouraged biotech-companies to have their stocks listed. The majority of the currently quoted firms are involved into bio-pharmaceuticals and equipment and supplies. However, a strict differentiation might be rather difficult sometimes. Only one company can be assigned to the field of agro-food (cf. table 1.8).

Table 1.8: Biotechnology companies listed at the German stock exchange and industrial sector

Name of the company	Industrial sector
Cybio AG	Bio-pharmaceuticals, equipment and supplies
Girindus AG	Equipment and supplies
GPC AG	Bio-pharmaceuticals
KWS Kleinwanzlebener Saatzucht AG	Agro-food
Mologen Holding AG	Bio-pharmaceuticals
Morphosys AG	Bio-pharmaceuticals
MWG-Biotech AG	Bio-pharmaceuticals, equipment and supplies
November AG	Bio-pharmaceuticals, equipment and supplies
Qiagen AG	Equipment and supplies
Rhein-Biotech AG	Bio-pharmaceuticals
Stratec Biomedical Systems AG	Equipment and supplies, bio-pharmaceuticals
Trace Biotech AG	Bio-pharmaceuticals, equipment and supplies

Regulatory environment

Political framework conditions applying for the German biotechnology concern general issues of the *Bürgerliches Gesetzbuch* (Civil Code), contract and trade laws, as well as legislation regarding genetic engineering in particular. There are quite many laws, ordinances, and regulations on genetic engineering, reflecting the importance of this technology for policy but also the high level of regulation in Germany. We show the most important legal documents on which regulation in biotechnology is based in Germany in Appendix C.

There has been one particular law that considerably affected commercialisation of biotechnology in the early years of the development of this technology. In 1990, the Federal Republic of Germany was the first industrialised nation to have a law governing genetic engineering (*Gentechnikgesetz*). Soon after the law had been promulgated complaints came up that due to the costly and time-consuming licensing procedures and stringent requirements prescribed by the law German science and industry could not keep pace with the dynamic development of biotechnology that had set in world-wide. Scientists and industrialists warned that competitive drawbacks might result.

Against this backdrop the German *Bundestag* adopted a resolution in late 1992 inviting the federal government to propose an amendment to the 'Genetic Engineering Act'. On the basis of this proposal the first law amending the 'Genetic

Engineering Act' was adopted in December 1993. Unreasonable and objectively unjustified restrictions and bureaucratic obstacles were sought to be abolished.

The most important results of amending the Genetic Engineering Act which now takes advantage of the framework provided by the overriding EU directives are a streamlined procedure:

- Licensing and registration deadlines at the lower safety levels 1 (no hazard) and 2 (low hazard) were shortened;
- Abolishment of the hearing previously required to involve the public when genetically modified plants are released. Applicants were thus relieved from an extremely costly and time-consuming procedure;
- Abolishment of licences for the exchange of research results and for clinical trials;
- Specification of the scope of the law: it was made perfectly clear that the Genetic Engineering Act does not cover the performance of genetic engineering procedures in man.

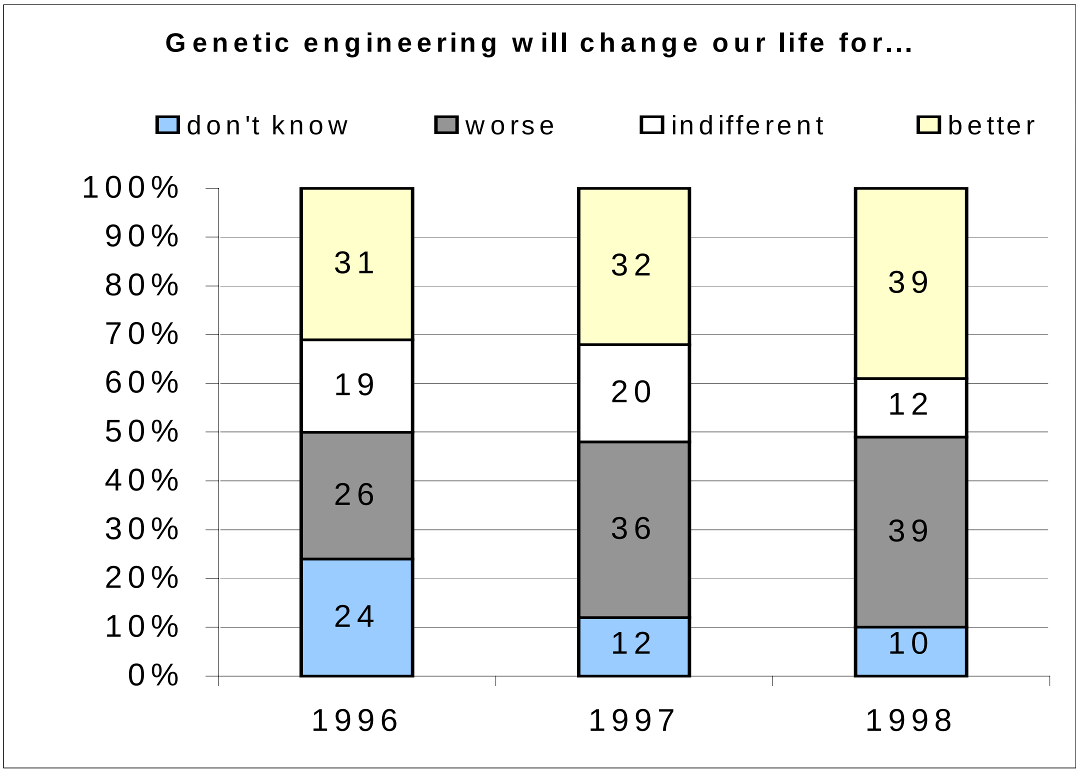
The government considers "the successful deregulation of genetic engineering" as an example demonstrating that "the legal framework in a given area of research has a crucial impact on the attractiveness of a country for research and production" (BMBF 1999). Although we agree with the statement that the legal framework does have some effect on exploitation of a technology, we argue that it had merely a minor direct influence in this case. Other factors, such as the general lack of awareness among industry, science and policy of this key technology in the early years of development, might better explain the late start of commercialisation of biotechnology in Germany.

Two EU directives of 1990 are important for the biotechnology area in Germany. One of the directives (90/219/EWG) regulates the treatment of GMOs in closed rooms, the other (90/220/EWG) concerns the release and trade of GMOs. They comprise detailed instructions which were translated into national law by the genetic engineering act (see above). Both directives were adjusted and adopted to recent technological advances in 1994. The former was changed by the directive 94/51/EG and the latter was altered by the directive 94/15/EG. Recently, appendix III of the directive 90/220/EWG was changed by the directive 97/35/EG. Further more, directive 90/219/EWG was altered by the directive 98/81/EG (6 October 1998). This directive has to be translated into national law until 5 June 2000 and mainly concerns the adaptation of the administrative procedures according to the actual risks of the operations undertaken on GMOs. These GMOs will be divided into four instead of two safety levels in future.

Acceptance of biotechnology

Development and application of modern biotechnology in medicine/ pharmaceuticals and Agro-food are accompanied by a controversial public debate on benefits and risks of this technology. Public acceptance is likely to play an important role in future development of biotechnology in Germany. On the one hand public acceptance and leading PINGO's influence political institutions in creating general framework conditions that may inhibit or encourage the use of biotechnology in research and industry. On the other hand consumer's acceptance of products related to modern biotechnology and genetic engineering act as indicator for their willingness to buy these products and therefore has great influence on decisions of related industries. In general, industry and politics have a tendency to support modern biotechnology for the reasons of keeping up international competitiveness and creating new jobs, whereas critics are concerned about risks for environment, health of consumers and ethical aspects.

Figure 1.6: Public attitudes towards genetic engineering in Germany



Source: European Commission 1997; Hampel et al. 1997; Rieder 1999

Public perception of modern biotechnology and genetic engineering has been studied in three EUROBAROMETER surveys, carried out in 1991, 1993 and 1996 on behalf of the European Commission. In the European context Germans have a rather sceptical view on biotechnology and especially on genetic engineering. In 1996 40 % of the Germans think that biotechnology will positively influence their life compared to 50 % in the EU average. Considering genetic engineering optimistic expectations are even lower with 32 % compared to 43 % of the European average (European Commission 1997). However it can be realised that the percentage of people having negative expectations is even higher in other countries such as the Netherlands, Denmark, Austria and the UK.

According to the Eurobarometer survey carried out in the year 1996 there has been found a U-relationship related to the attitudes towards genetic engineering in Germany: after a noticeable slump between 1991 and 1993 (from 44 % to 26 %), the percentage of optimists rose again to 32 % in 1996 (European Commission 1997). In spring 1997, after the birth of the cloned sheep "Dolly", people expecting negative implications of genetic engineering (36 %) exceeded those expecting benefits from this technology (32 %) (Hampel et al. 1997). A further polarisation of the public attitude towards genetic engineering can be registered in surveys carried out in the year 1998 (figure 1.6).

Future trends

In future the federal government's research policy is supposed to focus more than before on general legal conditions to detect possible inhibiting regulations earlier.

A notable general feature of the German biotechnology promotion is the rather flexible construction of the promotion fields which should also apply in future, e. g. in case of the programme "Biotechnology 2000" the definition of the promotion fields can be adapted to actual necessities. On the other hand, the programmes mostly include both top-down and bottom-up approaches. A general trend in this context is the focus on technology transfer and commercialisation.

As detailed figures for most funding organisations and their programmes are not available and according to the limited statistical material for the whole period 1994 to 1998 it is not possible to discuss trends within different areas of biotechnology. However, the experts interviewed expect that the following research fields will be important in the near future: development of basic biotechnologies (area B7) as well as of human and veterinary diagnostic (area B6) (Gießler und Reiß, 1999, p. 30).

2. Bio-pharmaceuticals

2.1 The science base

2.1.1 Public organisations/charities involved in carrying out research

Almost all universities in Germany with science or medical faculties are doing some kind of research with relevance for the bio-pharmaceutical sector. According to a survey performed by the German Federal Statistical Office (1995), there have been about 450 university institutions involved in biotechnological research in Germany in 1992. The most important non-university research organisations are those of the FhG, the MPG, the HGF and the WGL.

Institutes of the organisations mentioned above which carry out bio-pharmaceutical research are summarised in table 2.1. The number of institutes in this sector is considerably larger compared to the other areas. The establishments of the MPG are particularly active in this field.

Table 2.1: Non-university institutions involved in research relevant to the bio-pharmaceutical sector

Name	**Location**	**Research Organisation**
Surface Technology and Biochemical Engineering IGB	Stuttgart	FhG
Toxicology and Aerosol Research ITA	Hanover	FhG
Biochemistry	Martinsried	MPG
Biology	Tübingen	MPG
Brain Research	Frankfurt	MPG
Cell Biology	Ladenburg	MPG
Chemistry	Mainz	MPG
Evolutionary Biology	Tübingen	MPG
Experimental Medicine	Göttingen	MPG
Friedrich-Miescher-Laboratories for biological working groups	Tübingen	MPG
Immune Biology	Freiburg	MPG

Name	**Location**	**Research Organisation**
Infection Biology	Berlin	MPG
Medical Research	Heidelberg	MPG
Molecular Physiology	Dortmund	MPG
Molecular Genetics	Berlin	MPG
Neurological Research	Cologne	MPG
Neurophysiological Research	Leipzig	MPG
Physiological and Clinical Research	Bad Nauheim	MPG
German Cancer Research Centre (DKFZ)	Heidelberg	Helmholtz Centres
Research Centre Jülich (FZJ)	Jülich	Helmholtz Centres
Gesellschaft für biotechnologische Forschung (GBF)	Braunschweig	Helmholtz Centres
Max-Delbrück-Centre for Molecular Medicine (MDC)	Berlin-Buch	Helmholtz Centres
Neurobiology (IfN)	Magdeburg	WGL institutes
Molecular Biotechnology (IMB)	Jena	WGL institutes
Molecular Pharmacology (FMP)	Berlin-Friedrichsfelde	WGL institutes
Primate Centre (DPZ)	Göttingen	WGL institutes
Micro-organisms and Cell Culture (DSMZ)	Braunschweig	WGL institutes
Centre of Excellence for biocatalysis and biotransformation	Düsseldorf	University and Helmholtz Centres

Source: BMBF 1999

In addition, there are several organisations with departmental research tasks on behalf of federal ministries, the AiF, and the European Molecular Biology Laboratory (EMBL) in Heidelberg (Gießler and Reiß, 1999).

The 'departmental research organisations', are connected directly to ministries of the *Länder* and the federal government (BMBF 1999). These institutes often carry out general activities for the respective ministries in addition to R&D service. Compared to their counterparts in other countries, German departmental research institutes account for a relatively small share of total publicly funded R&D. Nevertheless, they often play an important role in the R&D landscape; some of them are leaders in special R&D sectors (Schmoch et al. 1997).

The purpose of the EMBL is to do basic research in biosciences, foster technical developments in co-operation with firms, provide service facilities for other research organisations, and offer teaching and training activities. With two outstations (at the DESY, Hamburg and at the ILL, Grenoble) it is one of the centres of excellence in Europe. The federal government funds EMBL research with approximately 10 million € per year. Research activities focus on structural biology and cell biology, cell differentiation, genome structure, gene expression and evolutionary biology (BMBF 1996).

2.1.2 Public organisations/charities involved in funding

The main funding organisations in the bio-pharmaceuticals area are the BMBF and the BMG.

2.1.2.1 The BMG and its funding programmes

The BMG's departmental research activities are application-oriented and intend to generate knowledge related to departmental functions, to disseminate the concepts underlying political and administrative decisions and to evaluate BMG schemes aimed at properly fulfilling departmental tasks. In its departmental research the BMG mainly uses the following instruments:

- pilot projects including project funding;
- departmental research by subordinate institutions and basic funding of non-university research institutions (e. g. *Bundesinstitut für Arzneimittel und Medizinprodukte* [BFAM - Federal Institute for Drugs and Medical Devices] and Robert Koch Institute).

The priorities of the BMG's departmental research mainly deal with disease-related departmental research, telematics in the health care system and telemedicine, evaluation of medical diagnostic and therapeutic procedures, quality assurance and health reporting and are therefore less relevant for our purpose.

The programme 'Health Research 2000' under joint auspices of the BMBF covers biotechnology to some extent. Among others it includes clinical research in certain diseases, which has some relation to biotechnology (Gießler and Reiß, 1999). The primary objectives of the programme are

- to promote health and to combat disease and
- to improve the structures of health research

2.1.2.2 The BMBF and its funding programmes

The BMBF funding within the Health Research 2000 framework has a dual thrust:

- in terms of content the objective is to obtain research results that meet international top standards and to take advantage of innovation opportunities at the clinical and industrial levels and in the health care system,

- in structural terms the objective is to create, maintain, improve and network research potentials that are attractive for international science and industry, especially the pharmaceutical industry.

Another important task is to contribute towards an efficient and affordable health care system. BMBF funding within Health Research 2000 covers four major sectors:

- biomedical research, especially basic research and research into the causes of disease,
- clinical research for the improved diagnosis and control of diseases,
- research and development in the field of medical technology,
- public health research and epidemiology including research into health care systems.

The objectives of BMBF general funding in terms of structure and content are attained through various funding instruments, i. e.

- through project funding which supports activities with a thematic definition and timeframe and serves to take up and establish new research ideas by providing start-up funding, to stimulate competition and to improve the structures in university and non-university science systems;
- through providing basic funding for non-university research institutions to tackle supraregional long-term research tasks and create a permanent basis for important research activities as well as to develop an internationally attractive research competence.

Thematic priorities of the BMBF funding related to bio-pharmaceuticals are in the following areas:

a) Biomedical research
Biomedical research receives increased funding in the fields of

- Cancer research: The greatest contribution to cancer research is made by the medical departments of universities which in the clinical sector are supported by tumour centres. Important contributors in the non-university research sector are the *Stiftung Deutsches Krebsforschungszentrum* (DKFZ – 'German Cancer Research Centre') and the *Stiftung Max Delbrück-Zentrum für Molekulare Medizin* (MDC – 'Max Delbrück Centre for Molecular Medicine'), which are both foundations.
- Cardiovascular research: Activities in this field focus on preventive and risk factor research which was first launched through project funding (e. g. 'German Cardiovascular Prevention Study') but has meanwhile become established in the higher education sector and in non-university institutions, especially the HGF

centres, the MDC and the GSF - *Forschungszentrum für Umwelt und Gesundheit* (GSF – 'Research Centre for Environment and Health').

- Molecular medicine: The new molecular biology approach is established in the entire field of biomedical research, with the MDC serving as a hub for the quick transfer to clinical research BMBF funding contributes to research with its priorities "Gene therapy I and II". From 1998 onwards, five selected activities will be supported under the pilot project "Diagnosis and therapy supported by molecular medicine".

b) Clinical research

In clinical research BMBF funding is mainly intended to achieve structural goals geared to co-operation, networking and competition:

- Interdisciplinary clinical research centres: Under an eight-year funding scheme whose annual financial volume will decrease over the years efficient organisational structures for interdisciplinary clinical research should be built up at eight universities.
- Co-ordination centres for clinical studies at universities: This funding programme was initiated to provide start-up funding for medical departments to set up co-ordination centres which should prepare, perform and evaluate clinical studies across universities. The purpose is to make good a deficit of clinical research
- Competence networks for medicine (MedNet): Disease-related competence networks should transfer the results of leading-edge research as quickly as possible to patient care centres and - vice versa - questions from patient care centres to research It is intended to set up horizontal links between working groups of different disciplines and vertical links with highly qualified patient care institutions.
- Infectious diseases: In this area funding is provided for 18 co-operative research projects aimed at discovering the pathogenesis of bacterial and viral diseases related to the emergence of new pathogens (e. g. BSE) as well as at controlling infectious diseases like AIDS and hepatitis which are of particular importance in terms of health care policy. Research in the fields of tropical medicine and parasitology enjoys special support.

c) Medical technology

The BMBF's funding schemes are co-ordinated under the Health Research 2000 programme (see above), while activities are implemented and financed under the specific programmes on information technology, laser research, materials research, microsystems and biotechnology. Among the recipients of basic funding are the *Institut für biomedizinische Technik* (Institute for Biomedical Technology) of the FhG and five HGF centres and in particular the 'Karlsruhe Research Centre'. A specific problem encountered with this type of funding is the implementation of innovative medical technology products in the regulated health care market under general cost cutting conditions.

The 'Biotechnology 2000' programme of the BMBF is another major funding scheme with relevance to bio-pharmaceuticals and comprises a number of funding priorities (cf. ch.1.3). The purpose of Biotechnology 2000 is to extend the scientific basis and to push technological development. It aims in particular at intensifying the application of biotechnology. Unfortunately, it was not possible to properly divide the thematic priorities into our three categories 'bio-pharmaceuticals', 'agro-food' and 'equipment and supplies'. However, the ones that are partly or completely relevant for the bio-pharmaceuticals sector will be described subsequently.

The *human genome research (project)* completely belongs to our definition of the bio-pharmaceuticals sector as it comprises the following subjects:

- exploring the structure and function of the human genetic code;
- developing new possibilities of fighting severe diseases such as cancer, cardiovascular disorders and Alzheimer's disease;
- establishing new demand-driven technology transfer models.

The *BioMethods* area of 'Biotechnology 2000' includes biotechnology methods and processes and thus is of partial interest for bio-pharmaceuticals (most of the projects funded in this area should belong to our equipment and supplies sector – see below):

- designing and automating parallel working steps in genome research;
- developing better and more reliable screening processes for natural compound research to identify interesting pharmaceutical structures;
- devising combinatory and evolutionary biological synthesis strategies;
- developing research methods and processes to replace animal testing;
- developing methods and processes for the safe use of organisms and biological techniques.

2.1.3 Total biotechnology research funds allocated to the sector

In a recent study, the national biotechnology funding activities were differentiated into eight areas (Reiß 1999; table 2.2). The funding area B6, 'diagnostic and therapeutic systems for human/veterinary purpose', seems to be most relevant to the bio-pharmaceutical sector studied in this chapter. The development of human or veterinary diagnostics, was ranked third in the funding priority. It received around 10 % of the approved funds in the period 1994 to 1998 (Gießler and Reiß, 1999). In this area the promotion of R&D is largely dominated by funding of the BMBF and

BMG with the programmes 'Biotechnology 2000' and 'Health Research 2000' as described above. Funding in this context is directed mainly to sub-area 6.1 (immunology, therapeutics and diagnostic antibodies). Other sub-areas being funded are human genome mapping (sub-area 6.3), human gene transfer techniques (sub-area 6.4), as well as DNA diagnostics (sub-area 6.8). Due to limited data availability for all programmes besides 'Biotechnology 2000', it is not possible to describe in more detail the publicly funded research in the other sub-areas.

Nevertheless, one can assume that beside the programmes of the BMBF and BMG, additionally research is promoted by the DFG, the AiF, the *Länder* ministries, and the *Stifterverband der Deutschen Wissenschaft* (word-for-word translation: Donator Association of the German Science).

Table 2.2: List of areas and sub-areas of biotechnology relevant for the bio-pharmaceuticals sector according to Reiß (1999)

B.6	**Developments of human/veterinary diagnostic, therapeutic systems**
6.1	immunology, therapeutic and diagnostic antibodies
6.2	vaccinology
6.3	human genome mapping
6.4	human gene transfer techniques
6.5	therapeutic proteins and oligonucleotides (substitutes for pharmaceuticals)
6.6	tissue engineering
6.7	genomics in drug discovery (substitutes for pharmaceuticals)
6.8	DNA diagnostics
6.9	forensics (genetic fingerprinting)

Source: Reiß (1999), p. 50

To value the amount spent for each of the eight categories, Gießler and Reiß (1999) first calculated the total of each funding area (B1-B8) according to the identified programmes and activities (yielding a recorded amount of 2,505 million €). These numbers were then set into correlation to the presumed national biotech funds of 3,021 million € assuming that the distribution among the budget of the funding areas (B1-B8) found in the former calculation remains constant (thus interpolating the numbers in relation to the total). The estimation values of biotechnology funding for area B6 is given in table 2.3. The overall budget is by far the highest of the three sectors under consideration. Funding by the Biotechnology 2000 scheme (61 million €) and by AiF-research (2 million €) is negligible compared to the amount of money granted within the Health Research 2000 framework (1,305 million €).

Table 2.3: Rough estimates of money spent on funding area B6 during 1994 and 1998

Programme/Activity	**Biotech budget 1994 - 1998 (million €)**
Biotechnology 2000: project funding (recorded)	61
Health Research 2000 (recorded)	1,305
AiF-Research (recorded)	52
Total (recorded)	1,418
Total (interpolated)	1,710

Source: Gießler and Reiß, 1999; own calculations

2.1.4 Special programmes for university-industry research collaboration

There are mainly two schemes that are relevant in the context of publicly supported research collaborations in the bio-pharmaceuticals sector in Germany: the 'Human Genome Research Project' and the 'Gene Centres' (cf. chapter 1.2).

The Human Genome Research Project has been established in 1997. This project aims at the systematic and comprehensive patenting of research results, thus ensuring the efficient and target-oriented translation of the research results into innovative products and services. Essential structural elements of this model are a patent and licence agency and a central database.

Relations between all partners are subject to contractual provisions and aimed at achieving mutual benefits. Until now, a number of patents are pending, and around 15 new businesses spawned by the Human Genome Research Project were founded until 1998. Current financial planning provides for about 100 million € for the project up to the year 2003.

The establishment of the Gene Centres has made a considerable contribution to force the linkage between industry and public research organisations. An important function of the Gene Centres is to act as focal points for co-operative research sponsored by the BMBF and research commissioned by the private sector. Thereby the aim is to encourage close co-operation and technology transfer between science and industry and to foster commercialisation (Gießler and Reiß, 1999)

Gene Centres exist in Cologne, where Cologne University is collaborating with the Max Planck Institute for Plant Breeding and Bayer AG; in Munich, where the

University of Munich is collaborating with Hoechst, Wacker Chemie, and the Max Planck Institute for Biochemistry; and in Heidelberg, where BASF co-operates with the University of Heidelberg. The fourth Gene Centre is a co-foundation of Schering and the senate of Berlin, where BMBF supports R&D through project funds. In 1995 BMBF funding ended and the respective research organisations and the host *Länder* started to finance their centres independently (BMBF 1996).

Another form similar to the Gene Centres are the 'centres of excellence'. The one relevant for the bio-pharmaceuticals sector was set up in Düsseldorf (centre of excellence for biotransformation; table 2.1) (Warmuth 1991).

2.1.5 National involvement in Framework (no.IV) programmes

We found that data on monetary involvement of German researchers in the IV. framework programme are not published (i. e. the numbers are collected by the EU but not shared widely with other authorities). Alternative investigations resulted in the numbers presented in table 2.4. German researchers took part in 138 projects and co-ordinated 68 projects thereof. The funds granted to researchers in German institutions within BIOMED amounted to 50 million €.

Table 2.4: Involvement of German researchers in framework programme BIOMED

Granted projects with German co-ordinator	Granted projects with German participation	Funds granted to German partners [MEuro]
68	138	50

Source: EU Querschnittskontaktstelle (1999)

Success rates of German researchers in BIOMED were rather low compared to other programmes of the 4. framework programme. This also applies for the share of the total funds granted to German researchers, which was lower in BIOMED than in most of the other framework programmes.

2.2 Industrial structure

Via desk research, we have identified 260 companies which were potentially active in the bio-pharmaceutical sector. In response to our survey, we have received 70 questionnaires back that were partially or fully completed. 7 % of the 260 firms answered that they actually did not apply to our sector definition, or were excluded because they were merely sales organisations of larger groups from abroad.

Table 2.5: Overview of the German bio-pharmaceutical industry

Number of companies (extrapolated)	242
Number of employees (extrapolated)	9,450[7] (lower bound: 1,419[8])
Total turnover (extrapolated)	1,887 million € [9]
Total biotech turnover (extrapolated)	1,281 million €
Agencies funding research	BMBF, BMG, DFG, AiF, *Länder* ministries, *Stifterverband der Deutschen Wissenschaft*
Number of dedicated biotech institutes	28 (cf. table 2.1)
Number of master and PhD degrees awarded during 1994-1998	2,944 (cf. table 1.6) 808 (ibid.)
Regulatory authorities	*Bundesinstitut für Arzneimittel und Medizinprodukte* (BfArM, Federal Institute for Drugs and Medical Devices, Bonn)
Regulations	*Gesetz zur Regelung der Gentechnik* (GenTG, genetic engineering act) Law on Medical Devices (ordinance of medical devices (MPV), ordinance on distribution channels for medical devices (MPVertrV), ordinance on the mandatory prescription of medical devices (MPVerschrV), ordinance on the installation, operation and application of medical devices (MPBetreibV)) *Embryonenschutzgesetz* (EschG, law about the protection of embryos)

We thus estimated that there are around 242 companies in Germany which match our sector definition of the bio-pharmaceutical sector (table 2.5). The actual number could be lower, because we assumed that the rate of companies not applying to our sector definition (7 %) remains the same within "respondents" and "non-respondents". On the other hand, the actual number of companies in this area could also be higher because we might have missed some companies when screening several databases. However, we consider the number of 242 companies in the

7 Calculated by multiplying the number of companies in each category by the average number of employees in each category.

8 Calculated by multiplying the number of companies in each category by the lower boundary of employees in each category.

9 Total average turnover per company times 242 companies.

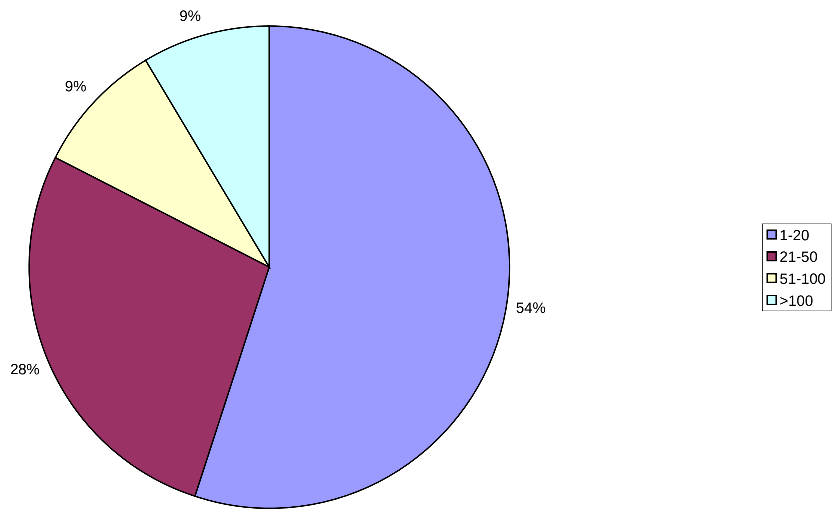
German bio-pharmaceutical sector as an upper bound. The numbers on employees (9,450) and industry turnover (1.8 billion € in total, 1.3 billion € in biotech) are based on this assumption and could therefore be biased upward as well. If the median is used to calculate the turnover rather than the average, total annual turnover amounts to 61 million €, and to 19 million € in biotech. Hence, the distribution of the annual turnover is heavily skewed to the right.

The sample

The following numbers refer to the sample of the 70 companies of the bio-pharmaceutical sector from which valid questionnaires have been received.

The size distribution in terms of employees is shown in figure 2.1. Most of the firms (54 %) are small firms employing 1 to 20 individuals. 28 % of the firms employ between 21 and 50 people whereas 9 % of the companies have a workforce of 51 to 100 and more than 100 people respectively (figure 2.1).

Figure 2.1: Size distribution in terms of employees of the companies in the bio-pharmaceutical sample



The majority of companies (59 %) were established independently. Around one third grew out of PSR and only some (9 %) were founded as a spin-off from another firm.

Only 43 % of the firms are older than three years, 61 % have been set up between 1994 and 1998. The median of turnover of the bio-pharmaceutical sample was 250,000 € in total and 80,000 € in biotech (32 %).

Most of the firms (51 %) achieve 100 % of their total annual sales in biotechnology. A relatively large number of companies (23 %) make less than 20 % of their annual turnover in biotechnology.

Taking all the data presented up to now together, we conclude that there are many firms solely involved into biotech (as they make 100 % of their total turnover in biotech), but generating relatively low annual turnovers still. On the other hand, there are other bigger (and older) pharmaceutical firms diversifying into biotechnology. Their average share of biotech turnover is less than in the core biotech firms but in terms of absolute numbers, they play the major role.

Table 2.6: Main product and service market of the bio-pharmaceutical companies in our sample

	Main product market	Main service market
Germany	41 %	49 %
European Union	33 %	31 %
USA	22 %	20 %

62 % of the companies in our sample actually sell biotech products. The main product market for 41 % of the firms is Germany, followed by countries in the European Union (33 %) and the USA (22 %). This division broadly also applies for services offered in biotechnology (table 2.6). 62 % of the firms offer services related to biotechnology, 42 % are contract research organisations (those firms which are solely CROs were excluded by the definition of the sector). Almost half of the sample (49 %) offer their services mainly in Germany. Europe emerged to be the main service market to 31 % of the companies and 20 % mainly focus on the US as a market place for their services. Other regions do not play a significant role. Only 12 % of the firms reported of licensing income.

On average, each company has between one and two patents providing national (31 %) or potentially international claims (30 %) on an invention. IPR restricted to Europe or the US tallied 22 % and 17 % respectively. Under the condition that a firm has at least one patent, the average number of patents is between 3 and 4. The high share of patents with the option on world-wide protection mimics the fact that the pharma industry is working internationally and might not be constrained to national boundaries. Together with the findings that (only) 62 % of the companies have sales in biotech and that there are very many start-ups not older than three years in the sample, this could give a hint on the phase in the life-cycle the companies are in at the moment, i. e. that they are preparing to exploit their inventions already patented on international markets.

86 % of the firms from this sector have reported of R&D collaborations either with organisations from PSR or with other companies. If collaborative R&D with PSR is concerned the partner for the firms in our sample is usually located in Germany (90 %). This fact should underpin the importance of geographical proximity for the establishment and success of collaborations in science often mentioned in studies on public-private networks. It further more is a rationale for national public funding because it emphasises the importance of a well-developed national science base even in a global business like bio-pharmaceuticals.

Regarding research co-operations with another company the partner is located in Germany in most of the cases (58 %). American companies play an important role and contribute more than one quarter of the research partnerships. This could have several reasons, e. g. scientific and commercial excellence due to the lead of American biotechnology, or a gain in reputation through a collaboration partner from the US.

The bio-pharmaceutical companies in our sample have a strong focus on the German market in both commercial and scientific terms. We expect an increasing relevance of the European and the American market in future as the companies proceed in the life-cycle.

BINGOs

We have identified six BINGOs particularly relevant for bio-pharmaceutical companies:

- Association of Researching Pharmaceutical Manufacturers (VFA; www.vfa.de; Bonn)
- Association of the Pharmaceutical Industry (BPI; www.bpi.de; Frankfurt)
- Federation of Drug Manufacturers (BAH; www.bah.de; Bonn)
- Association of German Biotechnology Companies (VBU; www.dechema.de/biotech/vbu.htm, Frankfurt)
- German Association of Biotechnology Industries (DIB; www.vci.de/dib; Frankfurt)
- Association of the German Diagnostics Industry (VDGH; www.vdgh.de; Frankfurt)

Three of them are completely dedicated to the sector (VFA, BPI, BAH) and three are also relevant for the agro-food and the equipment and supplies area (VBU, DIB, VDGH).

The VFA is the business association of 38 pharmaceutical manufacturers, representing about two third of the German pharmaceutical market and employing 76,000 people altogether. One particularity of these firms is that they heavily invest in pharmaceutical research.

The BPI represents the interests of its 300 member companies against federal and European policy makers, to elaborate political concepts and influence domestic and European regulations regarding drugs and public health care. Its subsidiary BPI Service GmbH organises seminars, workshops, social events and distributes information material for the pharmaceutical industry, including technical information on 6,300 drugs. It has a turnover of 1.5 million €.

The BAH represents the interests of 309 drug manufacturers producing drugs for the OTC market against the federal government, the federal parliament, as well as against organisations on the European level.

The VBU was founded in 1996 by 55 German biotechnology companies. It is part of the *Deutsche Gesellschaft für Chemisches Apparatewesen, Chemische Technik und Biotechnologie* (Dechema), a large non profit organisation in biotechnology. Until June 1999, the number of VBU member companies has risen to almost 180. The VBU tries to support the growth of the German biotechnology industry by "catalysing the co-operation" between domestic as well as domestic and foreign enterprises and scientific institutions and determine the commercial potential of scientific discoveries. It advises the companies by providing information and support ranging from the foundation of a new company to deal making and going public. The communication with the public and relevant actors is recognised as another major task of the VBU.

The DIB is the biotechnology branch of the Association of the German Chemical Industry (VCI), the VCI sector groups, and the VCI sector associations. DIB is the German member of the European Biotechnology Association EuropaBio. It represents the interests of biotechnology companies against politicians, authorities, other institutions, and the general public. It may also support the setting-up and development of small and medium-sized biotechnology companies in Germany.

The VDGH was established by 13 companies in 1977 to represent their interests. Today, there are 72 firms combined representing about 90 % of the diagnostics market in Germany. The VDGH works together with relevant ministries on the federal and *Länder* level, monitoring offices of the *Länder*, other BINGOs, e. g. the German Diagnostics Group (DDG) and the European Diagnostic Manufacturers

Association (EDMA) to influence legislation and to elaborate new guidelines in public health care and quality management and certification. Besides, the association informs and advises its members about recent issues in legislation (EC directives, legal liability, or the Genetic Engineering Act), scientific developments (quality management in the laboratory, software validation), business information (structure and future development of the health care system, cost containment plans, prescription fee acts, conferences and international co-operations), and standardisation.

2.3 Consumer attitudes and market demand

Market size and specific characteristics

The worldwide market of pharmaceuticals has been estimated to around 282 billion € in the year 1997. Around one third of the global market accounts to each USA and Europe (Jungmittag et al. 2000). Within Europe Germany represents the biggest market for pharmaceuticals valued to around 24,5 billion € in 1997 followed by France (21.1 billion €), Italy (13.2 billion €) and the United Kingdom (8.8 billion €). When interpreting these data it has to be taken into account that these figures are based on sales to "end-consumers" (i. e. patients through pharmacies or other distribution channels).

Based on figures on production level (i. e. sales of the pharmaceutical industry) the market of pharmaceuticals in Germany achieved a market size of 16.2 billion €, thus being the greatest market within Europe followed by France, Italy and the United Kingdom (BPI 1999). Compared to other European countries the pharmaceutical market in Germany showed a rather moderate growth rate between 1993 and 1998 (table 2.7), mainly due to cost saving activities of the health authorities.

Traditionally, the pharmaceutical companies located in Germany achieve a significant export surplus in this segment. Between 1993 and 1998 the exports of pharmaceuticals produced in Germany increased from 6.5 billion € to 13.2 billion €. In 1997 and 1998 Germany has been the most important exporting nation of pharmaceuticals worldwide followed by the USA, Switzerland the United Kingdom, and France. In 1997 around 37 % of the pharmaceuticals were exported to EU countries, 20 % to the USA (VFA 1999a). Although the imports of pharmaceuticals to Germany increased significantly as well, an export surplus of around 5.4 billion € was registered in 1998 (table 2.7).

Table 2.7: Market of pharmaceuticals in Germany 1993 to 1998

	1993	1994	1995	1996	1997	1998
Turnover (billion €)[1)]	13.2	13.8	15.2	15.6	15.4	16.2
Imports (billion €)	3.6	4.5	5.0	5.7	6.3	7.8
Exports (billion €)	6.5	7,5	7.8	8.6	10.5	13.2
Number of NCEs	25	21	26	36	44	36
Number of pharmaceuticals produced with the help of genetic engineering	16[2)]	23	n. a.	32	n. a.	48
Number of biotechnology related patents by German applicants	50	73	65	70	96	129
Expenditures of the health care system in Germany (billion €)	162.6	173.6	192.0	195.4	193.7	196.5
Health expenditures in % of gross national product	9.9	10.0	10.4	10.5	10.4	10.3

1) prices on production level
2) 1992

Sources: BPI 1999, CheManager 1999a, CheManager 1999b, CheManager, 1999c, VFA 1999a

The expenditures of the German health care system amounted to around 197 billion € in 1998 (table 2.7). This represents 10.3 % of the gross national product in Germany. In an international context the health related expenditures achieve around 14 % of the gross national product in the USA, while other European countries (e. g. United Kingdom, Spain, Italy, the Netherlands) have significantly lower costs in this area compared to Germany. From the year 1993 the absolute health care costs in Germany have been steadily growing until 1998 (table 2.7). When comparing the relative importance of health related expenditures a slight decline can be registered since 1996. This is mainly due to cost saving initiatives in the public health insurance system.

In analogy to the increasing relevance of genetic engineering as key technology in the discovery and development process of pharmaceuticals, a significant market growth can be observed as well for drugs which are produced with the help of this technology. Between 1996 and 1998 this type of drugs showed an impressive annual growth rate of 28 % to 730 billion € in 1998 (table 2.8). This equals to 4.5 % of the total market of pharmaceuticals in Germany. Within this group overproportional growth can be registered for recombinant vaccines and sexual hormones. Recombinant vaccines account for around 32 % of the sales volume of all drugs produced with the help of genetic engineering followed by drugs against diabetes (26 %) and immune stimulants (22 %), while the other groups (e. g. drugs against blood diseases, hormones, sexual hormones) achieve by far lower sales figures (table 2.8).

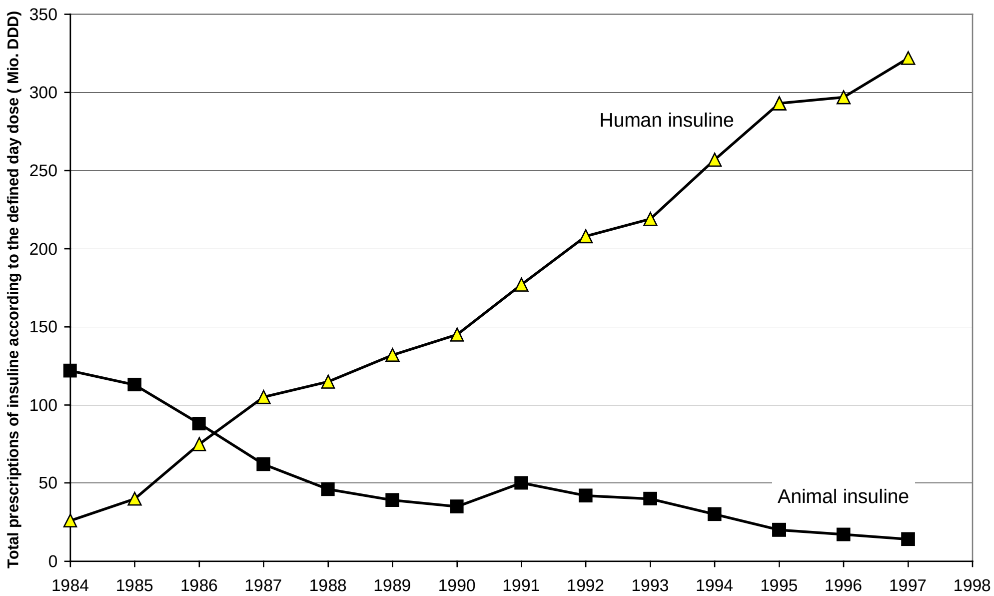
Table 2.8: Turnover of pharmaceuticals produced with the help of genetic engineering in Germany[1)] (million €)

Group of pharmaceuticals	1996	1997	1998	Annual growth rate
Vaccines	108.2	211.5	233.3	49 %
Drugs against diabetes	144.7	161.1	188.7	16 %
Immune stimulants	99.6	124.4	159.7	29 %
Drugs against blood diseases	49.8	58.5	60.9	12 %
Hormones (without sexual hormones)	46.3	54.9	56.6	12 %
Sexual hormones	7.3	17.1	22.0	76 %
Others	6.5	8.0	9.3	21 %
Total	**462.4**	**635.4**	**730.5**	**28 %**

1) Prices on production level, drugs sold in pharmacies

Source: VFA 1999a

Figure 2.2: Prescription of insulin in Germany from 1984 to 1997



Source: Schwabe and Paffrath 1999

Human insulin for the treatment of diabetes was the first therapeuticum produced with the help of genetic engineering which was introduced in the German market in 1987. Since its market introduction human insulins have replaced insulins produced from the pancreas of pork and cattle to a high extent. As shown in figure 2.2 the prescription of human insulins has grown steadily since 1984 to 322 million doses in the year 1997. In the same period the prescription of insulins from animal sources has declined from around 120 million doses in 1984 to 14 million doses in 1997.

For the coming years a further increase of the prescription of human insulin is expected mainly due to the growing number of diabetes patients in Germany.

Regulation policy

The authority concerned with the admission of drugs and medical devices in Germany is the *Bundesinstitut für Arzneimittel und Medizinprodukte* (BfArM, Federal Institute for Drugs and medical Devices, Bonn). It is an independent Federal Office under the auspices of the Federal Ministry of Health (BMG). 700 employees supervise

- the admission of drugs
- the registration of homeopathic drugs
- the registration of undesired averse effects
- the legal trade of anaesthetics and basic materials
- investigations regarding safety, appropriateness and benefits of medical devices according to national and European legislation

Besides, the BfArM advises the federal government concerning safety of drugs and medical devices.

The most important legal bodies for the work of the BfArM are the Law on Medical Devices, the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and the ordinance (statute rules) relating to the Law on Medical devices (ordinance of medical devices (MPV), ordinance on distribution channels for medical devices (MPVertrV), ordinance on the mandatory prescription of medical devices (MPVerschrV), ordinance on the installation, operation and application of medical devices (MPBetreibV)).

PINGOs

The most important PINGOs in this sector are the consumer organisations. They are also active in the two other EBIS sectors.

The *Verbraucher Initiative e.V.* is the largest consumer association in Germany. More than 9,000 members and 76 groups work as a lobbying organisation and advice their members about healthy nutrition, eco-friendly consumer goods, and legal issues. One of their projects (TransGen) is concerned about labelling and transparency of genetic engineering and food. Respective information is disseminated via a specific web-site (www.transgen.de).

The *Deutsche Tierschutzbund e.V.* (German Association for Animal Protection) was founded in 1881 as an umbrella organisation of animal protection societies and animal homes in Germany. Currently, there are 16 associations in the Länder and 700 local societies covering 400 animal homes and 700.000 members. It is thus the largest umbrella organisation for animal protection in Germany and Europe.

The *Bundesverband Tierschutz e.V.* (Association for Protection of Animals) was founded in 1961 and is the second largest umbrella organisation for animal protection in Germany, representing 100 societies and individuals. It advises committees of the federal ministry of nutrition, agriculture and forestry, or several foundations to reduce the number of animal trials and improve the conditions of the animals in those tests.

The *Bundesverband der Tierversuchsgegner – Menschen für Tierrechte e.V.* (Association of Opponents against Animal Trials – Humans for Rights of Animals) was founded in 1982 and acts as an representative of the rights of animals. Their aim is to incorporate the rights of animals in the basic law in Germany and elsewhere.

Social Acceptance in the Health Sector

The sector of bio-pharmaceuticals is strongly related to medical applications. Assessment of use of genetic engineering in this field may therefore act as indicator for public acceptance. In the Eurobarometer survey carried out in 1996, genetic testing and recombinant pharmaceuticals have been evaluated as being useful, morally acceptable and to be encouraged in Germany (European Commission 1997). This result corresponds to the national Biotech-Survey conducted in 1997. More than 60 % of the respondents agree to the medical applications of genetic engineering e.g. for producing vaccines or in therapy of cellular diseases. Since then the percentage of supporters went up to 75 %, but at the same time an increase of 15 % of those seeing risks for society can be observed (Rieder 1999). On the other hand genetically engineered breeding of laboratory animals for purposes in pharmaceutical research is strongly disapproved by 43 %. Concerning clinical diagnostics a majority of 74 % supports this application which is even true for prenatal diagnostics with 61 % (Hampel et al. 1998).

There is no intensive public debate on xenotransplantation in Germany. The debate on this issue is mainly carried out by experts from science, industry and bioethics. However, it is suggested to use the remaining time until the application of xenotransplantation in the clinical practice to a broad societal opinion finding process and discussion (Petermann and Sauter 1999).

2.4 Prospects for the sector

The future development of the bio-pharmaceuticals industry in Germany will be influenced by scientific, economic, legal and financial factors. Federal and state innovation policy may further support the sector. It is arguable that appropriate measures should aim at improving the framework conditions for the commercial development of the maturing industry (rather than further increasing the number of companies).

German research organisations and companies are linked to the international scientific system. Global advances in pharmaceutical R&D will thus be transferred to German institutions as well. It is expected that in the mid term, the genes causing many of the most important diseases will be identified. The genesis of the diseases would then become clear, offering a wide area for new and better treatments. Although there have been severe setbacks for gene therapy, it is expected that it will become a powerful treatment option in the long term. A number of the fastest growing bio-pharmaceutical companies in Germany are working in this field. Modern biotechnology will also help to find improved ways of drug administration (e. g. regarding orally available insulin) and to develop more efficient production processes for the pharmaceutical industry.

There are quite a number of economic factors determing future prospects of the bio-pharmaceutical industry. Positive impulses may come from the trend at pharmaceutical companies to outsource certain stages in R&D, in the drug application process and in production, as well as from the ageing population in Germany (as the expenditures for drugs increase considerably with higher age). Cost containment pressure in the public health care sector may negatively influence the business opportunities of the bio-pharmaceutical companies and of their customers. It can be argued that only some firms will be able to take advantage of that growth potential. The market in Germany and Europe is still fragmented. Compared to their US counterparts, European companies may be hindered to exploit the full commercial potential of future scientific advances.

Legal factors concern the reformation process of public health care systems (the system in Germany has be changed by several laws four times in the last 11 years) and the harmonisation efforts regarding the European (and international) drug application process. Despite such deregulation efforts, there still are many barriers for a rapid liberalisation of the market.

The financial environment for the German top-tier bio-pharmaceutical companies seems to remain advantageous in future as the number of firms reporting advances in research phases and product sales should increase as well as the number of companies listed at the *Neuer Markt*. The high demand of the firms for financial resources should thus be backed by the strong supply of venture capital and institutional and private investors at the stock exchanges. However, many experts predict a consolidation process among German biotech companies in the coming years. Such firms with lower or negative growth rates may not be able to fund second or later financing rounds. Hence the gap between successful and rather weak firms should open up in future.

3. Agro-Food

3.1 The science base

3.1.1 Public organisations/charities involved in carrying out research

Quite a considerable number of universities in Germany with science or engineering faculties are doing some kind of research with relevance for the agro-food sector. The most important non-university research organisations which carry out research in the area of agro-food are those of the MPG, the HGF and the WGL (table 3.1).

Table 3.1: Non-university institutions involved in research relevant to the agro-food sector

Name	Location	Research Organisation
Marine Microbiology	Bremen	MPG
Max Delbrück-Laboratories	Cologne	MPG
Molecular Plant Physiology	Golm	MPG
Plant Breeding	Cologne	MPG
Terrestrial Microbiology	Marburg	MPG
Research Centre Jülich (FZJ)	Jülich	Helmholtz Centres
Plant Genetics and Crops (IPK)	Gatersleben	WGL institutes
Plant Biochemistry (IPB)	Halle	WGL institutes
Food Research (DIFE)	Bergholz-Rehbrücke	WGL institutes
Micro-organisms and Cell Culture (DSMZ)	Braunschweig	WGL institutes
Centre of Excellence for molecular biology of plant breeding and neurobiology	Hamburg	University

Source: BMBF 1999

In addition, there are several organisations with departmental research tasks on behalf of federal ministries and the AiF (Gießler and Reiß, 1999).

The departmental research organisations, are connected directly to ministries of the *Länder* and the federal government (BMBF 1996). These institutes often carry out general activities for the respective ministries in addition to R&D service. In the agro-food sector there are a number of departmental research organisations with links to the BML which also perform research in biotechnology. These include the *Bundesanstalt für Ernährung* (BfE, 'Federal Institute for Nutrition'), the *Biologische Bundesanstalt für Land- und Forstwirtschaft, Braunschweig* ('Federal Biological Research Centre for Agriculture and Forestry'), the *Bundesforschungsanstalt für Viruskrankheiten der Tiere* (BFAV, 'Federal Research Centre for Virus Diseases of Animals'), the *Bundesanstalt für Milchforschung* (BAfM, 'Federal Dairy Research Centre'), and the *Bundesanstalt für Züchtungsforschung an Kulturpflanzen* (BAZ, 'Federal Centre for Breeding Research on Cultivated Plants').

3.1.2 Public organisations/charities involved in funding

The main funding organisations in the agro-food sector are the BMBF and the BML. According to Gießler and Reiß (1999) the programmes that are relevant for this area are the programmes of 'Biotechnology 2000' and 'Renewable Resources'. The latter covers biotechnology to some extent and is under the responsibility of the BML. The federal government places around 27.7 million € annually at disposal for R&D in this context. 14 % of this budget (3.8 million €) are used for the promotion of biotechnological R&D approaches which include plant breeding to improve resistances and yields (29 % of the biotechnological R&D funds) as well as to produce plants with costum-made features (55 %), and the biotransformation of plant resources to special products (16 %) (FNR 1998).

The 'Biotechnology 2000' programme of the BMBF comprises a number of funding priorities (cf. chapter 1.3). Unfortunately, it was not possible to properly divide the thematic priorities into our three categories 'bio-pharmaceuticals', 'agro-food' and 'equipment and supplies'. However, the *BioProduction* (production systems of biotechnology) funding area should broadly overlap with our definition of the agro-food sector as it comprises the following subjects:

- integrating biological principles into technical production processes;
- improving expression systems for the volume production of characteristic and recombinant products;
- improving the synthesis performance of higher plants by applying molecular biology methods;
- activating endogenous and exogenous biological defence potentials to produce healthy crop plants.

3.1.3 Total biotechnology research funds allocated to the sector

In a recent study, the national biotechnology funding activities were differentiated into eight areas (Reiß 1999; table 3.2). The funding areas B1 and B2, 'plant biotechnology' (ranked second in the funding priority) and 'animal biotechnology' respectively, seem to be most relevant to the agro-food sector studied in this chapter. Both received around 5 % to 10 % of the approved funds of the 'Biotechnology 2000' programme in the period 1994 to 1998 (Gießler and Reiß, 1999).

Table 3.2: List of areas and sub-areas of biotechnology relevant for the agro-food sector according to Reiß (1999).

B.1	**Plant biotechnology (crops, trees, shrubs, etc.)**
1.1	reproduction and propagation
1.2	genetic modification introducing new/excluding existing genes (mono- and polygenic traits)
1.3	growing conditions
1.4	plant protection
1.5	plant pathogen diagnosis
1.6	genome mapping
1.7	biodiversity of plants in agriculture/horticulture
B.2	**Animal biotechnology, including**
2.1	reproduction
2.2	production
2.3	breeding, incl. genetic engineering in animals (creation of transgenics)
2.4	animal health care,
2.5	genome mapping
2.6	biodiversity of farm animals

Source: Reiß (1999)

In plant biotechnology (B1) most projects are funded in sub-area 1.2 (genetic modification) and sub-area 1.4 (plant protection). Additionally, a smaller part of the projects dealing with the sub-areas 1.1 (reproduction and propagation), 1.3 (growing conditions) and 1.5 (plant pathogen diagnosis) are supported. The sub-areas 1.6 (genome mapping) and 1.7 (biodiversity of plants and agriculture) play a negligible role in case of publicly funded research projects.

Funding in animal biotechnology (B2) is directed mainly to the sub-area 2.4 (animal health care). All the other sub-areas (reproduction, production, breeding, genome mapping, and biodiversity of farm animals) are less important in this context. Organisations contributing to funding in this area are the BMBF (programme Biotechnology 2000), the DFG and the Länder ministries. In addition, a certain contribution is made by the departmental research work of the BML (Gießler and Reiß, 1999).

An estimate of biotechnology funding for areas B1 and B2 according to Gießler and Reiß (1999, cf. chapter 2.1 for details) is given in table 3.3. Accordingly, departmental research of the BML contributed the major share of the budget of each area B1 and B2. Plant biotechnology (B1, 81 million €) received around 43 million € more by public sources than was devoted to the field of animal biotechnology (B2, 38 million €).

Table 3.3: Rough estimates of money spent on funding areas B1 and B2 during 1994 and 1998

Programme/Activity	**Biotech budget 1994 - 1998 (million €) area B1**	**Biotech budget 1994 - 1998 (million €) area B2**
Biotechnology 2000: project funding (recorded)	50	33
BML departmental research (recorded)	81	81
Renewable Resources (recorded)	19	0
Total (recorded)	150	114
Total (interpolated)	181	138

Source: Gießler and Reiß, 1999; own calculations

3.1.4 Special programmes for university-industry research collaboration

A centre of excellence relevant for the agro-food sector was set up in Hamburg. It focuses on molecular biology of plant breeding and neurobiology (Warmuth 1991). Two of the former gene centres, in Cologne and in Berlin, also had a focus on plant biotechnology and initiated some public research – industry collaborations. Federal funding of both centres ended in 1994 (Cologne) and 1995 (Berlin) respectively. All in all however, co-operation programmes funded by public sources are rather rare indicating the neglect of this field by federal policy. Recently, efforts have been made to improve this unfavourable situation by setting up *Leitprojekte* (cf. chapter 1.2) covering the agro-food sector.

3.1.5 National Involvement in Framework (no.IV) programmes

German researchers took part in 110 projects and co-ordinated 52 projects thereof. The funds granted to researchers in German institutions within BIOMED amounted to 61 million € (table 3.4).

Table 3.4: Involvement of German researchers in framework programme Agriculture

Granted projects with German co-ordinator	Granted projects with German participation	Funds granted to German partners [MEuro]
52	110	61

Source: EU Querschnittskontaktstelle (1999)

Success rates of German researchers in Agriculture were lowest relative to the success rates of German scientists in other programmes of the 4. framework programme. This also applies for the share of the total funds granted to German researchers, which was as low as in BIOMED.

3.2 Industrial structure

Via desk research, we have identified 64 companies which were potentially active in the German agro-food sector. In response to our survey, we have received 20 questionnaires back that were partially or fully completed. 13 % of the 64 firms answered that they actually did not apply to our sector definition, or were excluded because they were merely sales organisations of larger groups from abroad. We thus estimated that there are around 56 companies in Germany which match our definition of the agro-food sector (table 3.5). The actual number could be lower, because we assumed that the rate of companies not applying to our sector definition (13 %) remains the same within "respondents" and "non-respondents". On the other hand, the actual number of companies in this area could also be higher because we might have missed some companies when screening several databases. However, we consider the number of 56 companies in the German equipment and supplies sector as an upper bound. The numbers on employees (3,566) and industry turnover (610 million € in total, 210 million € in biotech) are based on this assumption and could therefore be biased upward as well. If the median is used to calculate the turnover rather than the average, total annual turnover amounts to 280 million €, and to 6.72 million € in biotech.

Table 3.5: Overview of the German agro-food industry

Number of companies (extrapolated)	56
Number of employees (extrapolated)	3,566 (lower bound: 1,998)
Total turnover (extrapolated)	610 million €
Total biotech turnover (extrapolated)	210 million €
Agencies funding research	BMBF, BML, *Länder* ministries
Number of dedicated biotech institutes	11 (cf. table 3.1)
Number of master and PhD degrees awarded during 1994-1998	3,002 (cf. table 1.6) 1,117 (ibid.)
Regulatory authorities	BML
Regulations	*Gesetz zur Regelung der Gentechnik* (GenTG, genetic engineering act) *Lebensmittel- and Bedarfsgegenständegesetz* (LMBG, law on food and consumer foods) Ordinance of the European Parliament of 27 January 1997 concerning novel food and novel food ingredients (97/258/EG) Ordinance of the European Council of 26 May 1998 on statements in addition to the ones requested by 79/112/EWG regarding labels on food containing GMOs (98/1139/EG) *Pflanzenschutzgesetz* (Plant Protection Law)

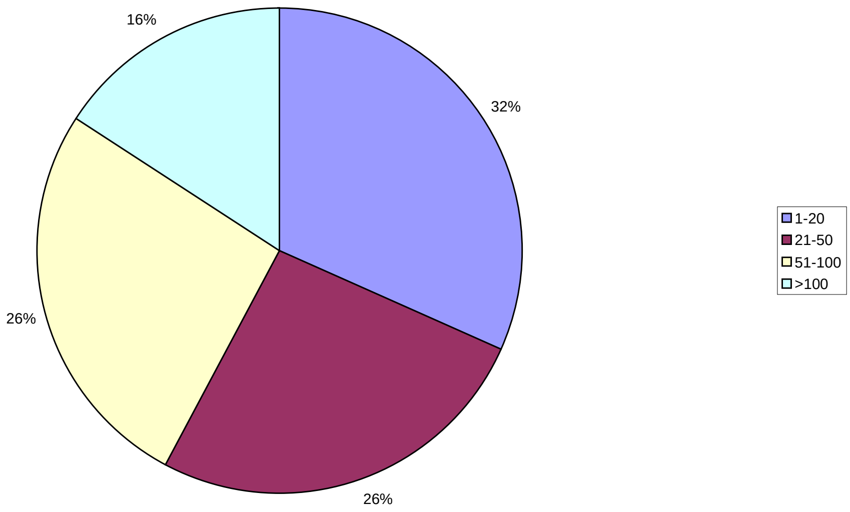
It turned out that there is no special law for genetically modified food, as food production and processing is regulated in general by the food law (*Lebensmittel- und Bedarfsgegenständegesetz*).

The sample

The following numbers refer to the sample of the 20 companies of the agro-food sector from which valid questionnaires have been received. Due to the low quantity of data in this sector we wish to particularly emphasise that statistics on such a data basis have to be taken *cum grano salis*.

The sample is relatively balanced regarding the size distribution of the companies represented by the number of employees (figure 3.1). Half of the firms in our sample were established independently, one quarter was either a spin-off from PSR or from another company respectively.

Figure 3.1: Size distribution in terms of employees of the companies in the agro-food sample



83 % of the firms are older than three years, 22 % have been set up between 1994 and 1998. The companies hesitated to provide numbers on turnover. The few answers indicated a large share of companies earning more than 10 million €. Merely a few firms generate more than 50 % of their total annual turnover in biotechnology. For most of the firms biotechnology is currently a business contributing below 20 % to the annual turnover.

42 % of the companies actually sell biotech products. Unfortunately we could not elucidate the main geographic market for the firms' sales in this area. Regarding services the domestic market is particularly important. Most companies conduct contract research as a part of their business. Only 16 % of the firms reported of licensing income.

On average, each company has between one and three patents providing national (32 %) or potentially international claims (21 %) on an invention. IPR restricted to Europe or the US is found in 29 % and 18 % of the cases respectively. Under the condition that a firm has at least one patent, the average number of patents is between 4 and 6.

Almost all firms from this sector have reported of R&D collaborations either with organisations from PSR or with other companies. If collaborative R&D with PSR is concerned the partner for the firms in our sample is usually located in Germany (96 %). This fact should underpin the importance of geographical proximity for the establishment and success of collaborations in science often mentioned in studies on public-private networks. It further more is a rationale for national public funding because it emphasises the importance of a well-developed national science base. However, we found evidence to believe that the German science base in the agro-food sector might not be entirely appropriate to meet the requirements of the firms (cf. chapter 5).

Regarding research co-operations with another company the partner is located either in Germany (45 %) or in other European countries (36 %).
The agro-food companies in our sample obviously have a strong focus on the German market mainly regarding scientific co-operations.

BINGOs

We have identified four BINGOs particularly relevant for agro-food companies:

- Industry Association Agrar e.V. (IVA; www.iva.de; Frankfurt)
- Federal Association of Plant Breeders in Germany (*Bundesverband Deutscher Samenkaufleute und Pflanzenzüchter e.V.*, Bonn)
- Federation for Food Law and Food Science e.V. (BLL; www.bll.de; Bonn)
- Association of German Biotechnology Companies (VBU; www.dechema.de/biotech/vbu.htm, Frankfurt)
- German Association of Biotechnology Industries (DIB; www.vci.de/dib; Frankfurt)

Three of them are completely dedicated to the sector (IVA, BDSP, BLL) and two are also relevant for the bio-pharmaceutical and the equipment and supplies area (VBU, DIB).

The IVA represents 59 companies from businesses like plant protection, fertiliser, and life science, employing around 20,000 people and generating sales around 4.4 billion € in 1997. It is a lobbying organisation.

The BLL represents the interests of its members versus the federal government and the federal parliament, state governments and state parliaments, as well as on European level (CIAA, the Organisation of the European Food Industries), and at the FAO and the WHO.

The tasks of the VBU and the DIB are described in more detail in chapter 2.2.

3.3 Consumer attitudes and market demand

Market size and specific characteristics

Agrobiotech products are targeted to the areas of agro-chemicals, seed, veterinary products and feed additives. Therefore, the situation and most important developments on these markets in Germany are characterised in the following.

Agro-chemicals

Table 3.6: International and German market for pesticides (billion €)

	1990	1991	1992	1993	1994	1995	1996	1997
Turnover world market	17.8	17.9	17.6	19.1	21.2	21.0	22.8	25.2
Turnover in Germany	0.77	0.94	0.76	0.70	0.73	0.90	0.94	0.98
Export of companies located in Germany	1.64	1.60	1.56	1.55	1.58	1.72	1.83	2.07

Source: Bassermann 1998

In 1997 the global market of pesticides accounted to around € 25 billion (table 3.6) of which 16 % are represented by Western Europe (v. Schlotheim-Schottelius 1997). In Germany, the turnover of pesticides increased until 1991 to € 0.94 billion and declined significantly in the following years, mainly due to extensivation and set-aside programmes of the EU (table 3.6). It took until 1995 that the domestic turnover of pesticides in Germany reached the level before the reform of the Common Agricultural Policy, while the exports of pesticides recovered faster and more significantly (table 3.6).

Worldwide and in Germany significant tendencies of concentration can be observed among agro-chemical companies. While in 1985 the leading 20 companies in this field represented around 83 % of the world market, the ten most important companies achieve a market share of almost 89 % of the world market (Bassermann 1998). These concentration tendencies are mainly caused by mergers and takeovers of international companies, often in the context of creating integrated life sciences companies. These activities have an influence on the German market as well, in which the six most important companies (BASF, AgroEvo, Novartis, Spiess-Urania, Rhône-Poulenc) control around two thirds of the market. For the coming years no significant increase in pesticide sales in Germany and ongoing merger and acquisition activities on an international level are expected from experts of the agro-chemical markets.

Seed

According to estimations of the International Seed Trade Federation, seed and plants are used worldwide with a value of around € 45 billion. Because a significant share of seed are produced by farmers themselves, the commercially relevant segment of seed market is estimated to around € 27 billion worldwide. Within the EU which accounts for around one third of the global market France, Germany, Italy and the United Kingdom represent the most important markets. In Germany, the internal commercial market of seed is estimated to around € 0.9 billion (ASSINSEL 1999).

Increasing concentration tendencies can be observed among the leading seed producing companies as well. In 1997 the top 10 seed companies controlled approximately 32 % of the global commercial seed market (RAFI 1998). In addition, increasing numbers of cooperation and takeovers took place between agro-chemical and seed-producing companies in recent years, mainly due to the expectation to compensate negative impacts of modern biotechnology on the pesticide market with increasing sales of transgenic seed. Although there are around 60 small and medium-sized seed-producing companies in Germany, the major company KWS AG achieved a turnover of around € 330 million in 1998.

Veterinary products and feed additives

In 1995 the worldwide animal health market is estimated to around € 11.8 billion of which nutritional feed additives achieve a market volume of € 2.9 billion, feed additives for veterinary purposes € 1.6 billion, and veterinary pharmaceuticals € 4.9 billion. The USA account for around 30 % of the world animal health market and Western Europe for another 25 %. The most important companies in this area are Mérial (a joint-venture of Rhone-Mérieux and Merck AgVet), Pfizer, Bayer, Novartis, American Home Products, Hoechst Roussel Vet and Hoffmann LaRoche. Important segments of the global feed additives market are amino acids (annual sales volume around € 1.5 billion), vitamines (€ 1.1 billion), carotinoids (€ 0.4 billion) and feed enzymes (€ 0.08 billion). There are very differing estimations concerning the veterinary products and feed additives market in Germany mainly due to differing segmentations of this field and the fact that more than 90 % of all products in this area generate annual sales of less than € 0.8 million per annum. Taken all together, the veterinary products and feed additives market in Germany should not exceed sustantially the border of € 0.8 billion.

Food

Both in terms of employment and production the food and beverages industry is one of the world's largest businesses. In the early 90s global sales of packaged food reached € 2.2 trillion per year (Christiansen et al. 1996). In 1995 the production of the EU food and beverages industry reached € 490 billion (European Commission 1995). In Germany, the food and beverages industry achieved a turnover of € 131.3 billion in 1998, which equals to around 12 % of the annual turnover of the producing industries in Germany. Around 11 % of the food and beverages produced in Germany are exported in particular to other EU countries (Statistisches Bundesamt 1999).

In 1998 around 556,700 people have been employed in the 5,944 food and beverages producing enterprises (with more than 20 employees) in Germany. In spite of the growing number of mergers and company takeovers in recent years, the food industry in Germany is still dominated by small and medium-sized companies: In the year 1995 72 % of the companies had less than 100 employees, around one quarter employed 100 to 500 people and only 3.1 % of the companies had more than 500 employees, representing 24 % of all people working in the food industry and achieving 26 % of the total turnover of the industry.

The situation of the food and beverages industry in Germany is characterised by the following aspects:

- Stagnation tendencies of food demand in Germany
- Growing segments of the food market (e. g. Functional Food, "biological" food) are compensated by decreasing turnovers in other segments (e. g. alcoholic beverages, meat, pasteurised milk)
- Individualisation of consumer behaviour
- Increasing relevance of retail brands (Ronke and Konrad 1999, Kornobis 1999)
- Globalisation of brands and adjustment of the brands portfolio in multinational companies (Biehl 1999)
- Growing competition mainly among the small and medium-sized companies of the food industry (e. g. influenced by increasing "purchasing power" of big food retailers)
- Traditionally low investments in R&D activities (Koschatzky and Maßfeller 1994)

The application areas of modern biotechnology is focused on those segments of the food and beverages industry in which the use of microorganisms, fermentation processes or enzymes traditionally plays a significant role. These segments are the dairy industry, the meat processing industry, the bakery industry, the production of alcoholic beverages and the production of enzymes as well as food additives (e. g. vitamins, aminoacids). In addition, modern biotechnology plays an increasing role in food analytics.

Only very few food products which are directly produced by modern biotechnology or genetic engineering approaches have been introduced in the EU market so far (e. g. ZENECA's tomato puree on the basis of genetically engineered tomatoes in the UK). Of much higher relevance is the use of starter cultures, enzymes and food additives which are produced or optimised with the help of modern biotechnology. In particular in the production of enzymes genetic engineering approaches play an increasing role: an overview of commercially available enzymes used in the food and beverages industry which are produced with the help of GMOs is given in table 3.7. In recent years the most important producers of enzymes have established genetic engineering as core technology in enzyme production. The targets are to reduce production costs, to produce new enzymes with the help of new traits, to shorten the time of development, to increase production safety as well as to optimise the functional characteristics of enzymes. Although currently around 60 % of all enzymes are produced with the help of GMOs worldwide, only few enzymes are commercially available for food processing which are produced with GMOs (table 3.7). There are no actual figures or estimations available concerning the market relevance of these enzymes in Germany. Nevertheless, in the coming years a strong increase in the application of recombinant enzymes in the food and beverages industry is expected by German experts (Menrad et al. 1999, Hüsing et al. 1997).

Table 3.7: Examples of commercially available enzymes produced with the help of genetically engineered organisms

Enzymes	**Application area in food and beverages industry**
α-amylase	bakery, brewery, starch saccharification, distillery
Chymosine	dairy industry, production of cheese
β-glucanase	brewery industry
α-glucane-transferase	starch saccharification
Glucose-isomerase	starch saccharification
Glucose-oxidase	bakery, flour-, egg processing, prod. of mayonnaise
Hemicellulase	Bakery
Catalase	production of mayonnaise
Lipase	processing of oil and fat
Maltose-amylase	bakery, brewery, dairy industry, distillery, processing of meat, fish and vegetables
Pullulanase	starch saccharification, brewery
Xylanase	bakery industry, processing of starch

Source: Jany and Greiner 1998

Another relatively new segment of the food market are so-called Functional Foods which do not only serve to satisfy hunger and the nutrient supply, but offer the consumers additional health benefits. Modern biotechnological approaches and procedures can be used in the production of Functional Foods as well. Due to differing definitions, the estimations concerning their market relevance in Europe differ between 1.3 to 1.5 billion €, of which around € 363 million are apportioned to Germany (Kutter 1998, Leatherhead 1998, Hilliam 1999). Currently, the market share of Functional Food is below 1 % of the food and beverages market in Europe and Germany. There are very positive estimations about the growth potential of Functional Foods but a 5 % market share seems to be the upper limit for this type of food in the medium term (Hüsing et al. 1999).

According to publicly available information, genetically modified microorganisms are not used in the food production and food processing industry in Germany. Due to the process-oriented character of modern biotechnology, it is very difficult to estimate the volume of the food and beverages market which is influenced by this technology. In general, experts assume that the food industry is the industry branch which has the highest substitution potential of traditional approaches and techniques through modern biotechnology. This substitution potential is currently estimated to around 10 % of the total turnover of the food industry in Germany valued € 114.5 billion in 1997 (Grupp et al. 1997).

PINGO's

Most of the PINGO's related to the biotechnology area are concerned with the uncontrolled release of GMOs to the environment as well as GMOs in food. There is quite a number of PINGOs in this area. In the following, we concentrate on the most important ones. Some of the subsequently listed organisations are also relevant to the other EBIS sectors (e. g. Greenpeace). However, we understand their main focus is applying to the agro-food sector.

The *Oeko-Institut* (Institute for Applied Ecology, Freiburg) was founded in 1977 in Germany. 80 scientists are working at the three German locations currently. This foundation was closely linked to the conflicts then surrounding the construction of nuclear power plants. The purpose therefore was to create a research institution independent of industry and governments, which orients its scientific work to ecological criteria and environmental considerations. The mission of the *Oeko-Institut* is to analyse and evaluate current and future environmental problems, and to develop and implement strategies and models for sustainable solutions, i. e. solutions which are ecologically sound, socially equitable and economically viable. Basic funding is entirely provided by membership fees and donations. The majority of the research projects are financed by mostly public clients. The Oeko-Institut has 4,500 individual members and 80 municipal members. Research at the *Oeko-Institut* encompasses the levels of basic research, conceptual development and implementation, as well as advisory and consultancy activities, and outreach to the media. The key areas of work are organised in Divisions encompassing Genetic Engineering, Chemical Industry, Energy, Environmental Law, Nuclear Safety and Transport. The main field of work of the Genetic Engineering Group is the utilisation of genetic engineering in agriculture and food production, where the impact of the release and distribution of GMOs is being analysed, mainly regarding health and ecological risks.

The *Gen-ethische Netzwerk e.V.* (gene-ethical network, Berlin) was founded in 1986 and collects, archives and disseminates information about genetic and reproduction technologies. It is thus also relevant to the bio-pharmaceutical sector. It publishes the journal *Gen-ethischer Informationsdienst* (gene-ethical information service, GID) and has a critical look at these technologies.

The international organisation of Greenpeace is quite active in Germany, comprising 2,000 honorary employees in 80 local groups. The focal points of their campaign regarding genetic engineering are the protest against patenting of life (e. g. the patent concerning the human germ line) and the utilisation of genetically modified crop in agriculture. They publish a list with food containing GMOs and try to concentrate the resistance of consumers versus genetically engineered food via their *Einkaufs-Netzwerk* (purchase network).

The *Bund für Umwelt und Naturschutz* (BUND, Association for Environment and Conservation) is a "forum of citizens" interested in the ecological condition of the earth. The BUND is divided in 16 associations in the *Länder*. In collaboration with big German department stores they organise special offer days for GMO-free food and consumer goods. In spring 1999 they initiated a campaign to prevent the cultivation of genetically modified crop on municipal land. The BUND is the German member of Friends of the Earth Europe (FoEE), the European branch of Friends of the Earth International (FoEI). FoEE is a network of 30 independent, national environmental organisations in 29 European countries. FoEE is involved in the sustainable development debate and promotes the need to change lifestyle and consumption patterns. With the project "Sustainable Europe", FoEE plans to reach a sustainable society on the national and European levels. FoEE co-ordinates and supports the campaigns and projects of its member groups, which besides biotechnology deal with subjects such as traffic, waste, recycling, EU-enlargement, sustainable tourism, EU structural funds, international financial institutions, trade and climate change. Through these activities FoEE aims to raise public awareness, to enhance the participation of people and environmental citizens organisations in political processes, and to influence political decision makers, especially on the European level.

Social Acceptance in the Agro-Food Sector

The application of modern biotechnology and genetic engineering is regarded rather critically in Germany. Despite the general sceptism related to this issue there are differentiations related to the purpose of the application. Genetically modified plants with improved resistance against insects or diseases are accepted by around one third of the respondents in a survey carried out in 1997. In contrast, the use of genetic engineering to increase the growth potential in plants is disapproved by more than 50 %. Applications in the food sector to genetically modify taste, appearance or shelf life of foods are flatly refused by three out of four respondents (Hampel et al. 1997).

A similar degree of differentiation is found in a survey conducted with experts of of science, industry, farmers and consumer organisations, critics of modern biotechnology as well as politics and administration. Whereas applications of modern biotechnology for analytical and diagnostic purposes in food production and processing are endorsed and even genetic modification of plants for food production or renewable ressources is assessed positively, methods of modern biotechnology in animal production (e.g. cloning, transgenic animals) are rejected (Menrad 1998). Corresponding results were obtained in a survey among German consumers on their readiness to buy genetically modified food (WBA Institut für Markftforschung und Marketingberatung 1996). Consumers have less concern about food produced or containing recombinant enzymes but especially genetically modified animal products won't be bought by a majority of consumers (table 3.8).

Table 3.8: Acceptance of genetically modified food

Food	Genetic Modification	"Would buy"	"Won't buy"
Jam	glucose syrup produced with recombinant enzymes	38 %	42 %
Potatoes	potatoes with inserted bacteria gene, do absorb smaller amounts of fat while frying	32 %	48 %
Bread, cakes, pastries	baking mixture contains recombinant enzyme	29 %	49 %
Cheese	produces by help of recombinant chymosine	29 %	50 %
Oil/ Fat	produced in herbicide resistant plants	28 %	47 %
Eggs	poultry fed with recombinant phytase containing feed	26 %	52 %
Tomatoes	prolonged shelf-life	25 %	56 %
Salmon	inserted genes for growth hormones	14 %	71 %

Source: WBA Institut für Marktforschung und Marketingberatung 1996

Controversy on genetically engineered food in Germany

Background of the debate

At least since the 90s there has been an intensive debate on the use of modern biotechnology in agriculture and food production in Germany. Often this debate was dominated by the risks and the disadvantages of this technology. During the mid 90s there was a rather aggressive debate concerning field trials with genetically modified plants. In 1995 six of 23 field trials were destroyed by militant opponents to genetic engineering in Germany (Riewenherm 1994, Strodthoff 1995a, b). During this phase industry complaint about the lack of political support.

Currently, the public debate about the use of modern biotechnology in the Agro-Food sector in Germany is still characterised by rather polarised positions between the supporters and opponents of this technology. On the one hand there are rather euphoric estimations and expectations of the German government and some representatives of science and industry, on the other hand there are rather sceptical and critical viewpoints especially from consumer organisations, churches and environmental groups. The German government has announced the target, that Germany shall become the number one in modern biotechnology and genetic engineering in Europe until 2000. Conversely, the German population is still rather critical concerning this issue.

Technology assessment activities

In Germany, the government and parliament had shown some concern for biotechnology application during the 80s. In this context hearings were conducted with domestic and foreign experts on issues such as scientific and technical development of biotechnology and its environmental and social risks. The application of participative technology assessment approaches in the biotechnology field can be traced back to the activities of the Commission of Inquiry (Enquête-Kommission) "Chancen und Risiken der Gentechnologie" of the German parliament, a commission of members of the parliament and scientific experts, which had the task to explore the scientific state of art to this topic and derive recommendations for politics. During this process several technology assessment activities have been carried out surrounded by intensive lobbying work of interest groups from economy, science and other fields (Ammon 1998).

During the 90s, the public debate on gene technology changed in a way that the application of this technology has become reality, especially in the pharmaceutical and agricultural field. In addition, a legislation process started in 1989 ending with the adoption of the German Gene Law in May 1990. In the following years the modification of this Law was intensively discussed in Germany until 1993, raising additional public interest in this topic. During this phase it was decided to carry out the participative technology assessment on herbicide-resistant plants (of the Wissenschaftszentrum Berlin) and the Bürgerforen in Baden-Württemberg. The first field trials with genetically modified plants in the mid 90s and the controversy on these activities raised the particular interest of the public in the application of gene technology in the Agro-Food sector. This discussion was a main impetus for the decision to carry out the discourse project in Lower Saxony (Saretzki 1998).

Participative technology assessment activities

The Ministry of Education and Research (BMBF[10]) funded a technology assessment project, which was carried out by the Wissenschaftszentrum Berlin (WZB) from 1991 to 1993. Industrial and environmental representatives were asked to participate in a round table discussion dealing with risks and benefits of herbicide-resistant plants. After two and a half years of discussion, the environmental representatives decided to terminate their participation, criticising the course of the debate (van den Daele 1994).

In two other discourse projects lay people and experts were involved in the discussion about the application of modern biotechnology in the so-called "Werkstattgespräche" and "Bürgerforen" which were organised by the Academy of Technology Assessment in Baden-Württemberg. In the "Werkstattgespräche" relevant organisations and interest groups were asked to discuss the application of modern biotechnology in plant production for non-food purposes, whereas in the "Bürgerforen" approximately 200 representatives of the general public were chosen randomly in three towns to discuss topics dealing with the application of genetic engineering for food production with experts for four days. After the discussion rounds the citizens were asked to decide on selected questions in this field, in order to get some information about the assessment of genetic engineering applications by informed people (Müller 1995; Kochte-Clemens and v. Schell 1995, Akademie für Technikfolgenabschätzung in Baden-Württemberg 1995).

Another discourse project was carried out in Lower Saxony in 1995/96 in which more than 170 persons of more than 100 different institutions discussed the use of genetic engineering. During this process different topics were discussed by experts and other participants in twelve workshops. The results of the discourse project were presented on a final seminar in May 1996 where additional experts from other federal states, representatives from different social groups, politicians, media and other interested people were invited to participate (Dally 1997).

Being aware that consumer acceptance is a basic requirement for successful application of genetic engineering in the Agro-Food sector, the German food industry started in 1994 to participate together with consumer and environmental groups in an "open" discussion process. Following the Dutch "informal consultations", Unilever Germany (Hamburg) invited the "Bund für Umwelt- und Naturschutz

---

10 There have been several renamings of this ministry during the last ten years. In this report we use the new official name given after the elections in September 1998.

Deutschland" (BUND), the "Verbraucherinitiative", the "Gewerkschaft Nahrung-Genuß-Gaststätten" and the "Hausfrauenbund" for informal meetings. The German consumer organisation "Arbeitsgemeinschaft der Verbraucherverbände" (AgV) and the "Gen-ethic Network" (Gen-ethisches Netzwerk) refused to participate because of the requirement of keeping all discussion topics and results confidential and the lack of ethical and social discussion aspects. In the meantime, due to increased work load, the Öko-Institut Freiburg has moved from active participation to advising the participating interest groups. The meetings are based on rules similar to those adopted by the Dutch model (Behrens et al. 1997).

In 1990 the German plant breeding company KWS Kleinwanzlebener Saatzucht AG established an advisory board of external experts form theology, ethics, molecular biology, agriculture, plant protection, sociology and technology assessment, in order to advice the company in questions related to the use of genetic engineering in plant breeding. The members of the board are individual persons and do not represent any specific organisation. Main topics of the discussion in the advisory board are related to all aspects concerning the use of genetic engineering in plant breeding and the release of genetically modified plants. In particular, the advisory board gives specific recommendations to field trials with genetically modified plants (Gaycken 1998).

Two basic forms of participative technology assessment or discourse models have been applied in the biotech field in Germany. These are the discourse of experts of different disciplines (e. g. in the WZB technology assessment, but also in the other approaches at least in parts of the activities) and the involvement of average citizens (which was practised in a formal way only in Baden-Württemberg). In Germany it can be expected that different forms of expert discourse activities will gain more relevance in future (also in the biotechnology field), since new scientific/technical disciplines will emerge – also with relevance for biotechnology – and the transdisciplinary discourse of experts has only been carried out in single cases. In addition, it is the target of the red/green government to stimulate discourse activities with average citizens. Taken all together, the participatice technology assessment and discourse activities carried out so far had no direct impact on politics or regulation in the biotech field in Germany. Because most of these activities had been restricted to a limited time and none was directly performed in the context of a specific political decision, it cannot be expected that such activities are able to result in fundamental changes in technical development.

3.4 Prospects for the sector

Modern biotechnology and genetic engineering are important tools in plant breeding in order to shorten the time of developing a new plant variety. Although there is an intensive public debate concerning Agro-Food biotechnology in Germany as well as in other countries of the EU, it can be estimated that genetic engineering approaches will be used for plant breeding due to cost saving reasons and shorter breeding intervals. In this context genomics activities (e. g. gene sequencing, functional analysis of genes, bioinformatics) will gain increasing relevance for the Agro-Food sector as well.

The future economic success of transgenic crops as well as the use of gene technology approaches in agriculture and food processing will depend to a high extent to the acceptance of these products and approaches by farmers, retailers and consumers. In addition, the "political and public climate" will be decisive for the future development of regulation in this field which plays a substantial role for the development and market approval of Agro-Food products related to modern biotechnology and genetic engineering. Since the mentioned groups have differing motives and attitudes in assessing such products, it is hardly impossible at this time to predict the market relevance of Agro-Food biotechnology in the coming years.

With relation to the involved actors in the innovation system of Agro-Food biotechnology, clear concentration tendencies emerge at least in the Agro-chemical, seed and Agro-veterinary industry. Compared to these areas, the food and beverages industry will remain rather segmented although increasing merger and take-over activities can be observed from a global as well as domestic viewpoint in this branch as well. NGOs of the consumer, environmental and animal welfare area will play an important role for the future use of modern biotechnology and genetic engineering in the Agro-Food sector. In this context it will be crucial to find new ways to constructively interact with these groups concerning this issue what was hardly the case in recent years in Germany.

4. Equipment and supplies

4.1 The science base

4.1.1 Public organisations/charities involved in carrying out research

It might be argued that almost all universities in Germany with science or engineering faculties are doing at least some kind of research with relevance for the equipment and supplies sector. However, it is difficult to estimate appropriate numbers with any accuracy. During 1994 and 1998 these academic institutions awarded 914 master and 165 PhD degrees related to this area (cf. chapter 1.3, table 1.6 for methodology).

Table 4.1: Non-university institutions involved in research relevant to the equipment and supplies sector

Name	**Location**	**Research Organisation**
Surface Technology and Biochemical Engineering IGB	Stuttgart	FhG
Environment-, Safety- and Energy-Technology UMSICHT	Oberhausen	FhG
Process Technology and Packaging IVV	Freising	FhG
Biological Cybernetics	Tübingen	MPG
Biophysics	Frankfurt	MPG
Biophysical Chemistry	Göttingen	MPG
Polymer Research	Mainz	MPG
Structural Molecular Biology	Hamburg	MPG
National Research Centre for Information Technology (GMD)	Sankt Augustin	Helmholtz Centres
Research Centre Jülich (FZJ)	Jülich	Helmholtz Centres
Society for Biotechnological Research (GBF)	Braunschweig	Helmholtz Centres
Molecular Biotechnology (IMB)	Jena	WGL institutes
Centre of Excellence for Bioprocessing	Stuttgart	FhG and University

Source: BMBF 1999

Table 4.1 lists those non-university institutes which carry out research in the area of equipment and supplies in biotechnology. They belong to the big research organisations in Germany: the FhG, the MPG, the Helmholtz Centres, and the WGL Institutes.

The main funding organisations in the equipment and supplies sector are the BMBF, the DFG, the AiF, and the *Länder* ministries.

4.1.2 Public organisations/charities involved in funding and their respective programmes

Although there might be more than one programme (and corresponding funding organisation) relevant for the 'supplies and equipment' sector, the main funding organisation discussed in this chapter is the BMBF. It came out to be quite comprehensive to delimit our definition of this sector from other related federal funding areas. Therefore merely the 'Biotechnology 2000' programme of the BMBF was taken into consideration. But still, as 'supplies and equipment' is not supported as an isolated sector, we can only describe those particular thematic priorities of 'Biotechnology 2000' which are to some extent relevant for the sector under consideration. This applies to BioMethods (biotechnology methods and processes), BioMatter (information contained in biological matter), BioSystems (biological functional systems for technology) and BioProduction (production systems of biotechnology) which are focusing on the following research agenda:

a) BioMethods
- Designing and automating parallel working steps in genome research;
- Developing better and reliable screening processes for natural compound research to identify interesting pharmaceutical structures;
- Devising combinatory and evolutionary biological synthesis strategies;
- Developing research methods and processes to replace animal testing;
- Developing methods and processes for the safe use of organisms and biological techniques.

b) BioMatter
- Identifying information principles (biological laws) embodied in biomolecules (DNA, proteins, glycosides etc.) to create a basis for innovations in health and environmental protection, agriculture and industry, and
- Developing a bioinformatics infrastructure.

c) BioSystems
- Technical implementation of biological principles at the interfaces with physics, chemistry etc.;

- Self-organisation of biological matter to form three-dimensional functional structures focusing on "Neuronal structures" (brain research) as a basis for innovations in information and communication technologies;
- Development of biological processes to reduce environmental pollution and clean up the environment.

d) BioProduction
- Integrating biological principles into technical production processes;
- Improving expression systems for the volume production of characteristic and recombinant products;
- Improving the synthesis performance of higher plants by applying molecular biology methods;
- Activating endogenous and exogenous biological defence potentials to produce healthy crop plants;
- Promoting the Jena Bioregion (bioinstruments).

4.1.3 Total biotechnology research funds allocated to the sector

In a recent study, the national biotechnology funding activities were differentiated into eight areas (Reiß 1999; table 4.2). The funding areas B4 'industrial biotechnology' and B7 'development of basic biotechnologies' seem to be most relevant for the equipment and supplies sector studied in this chapter. The latter received around 50 % of the approved funds in the period 1994 to 1996. The former was of minor importance (Gießler and Reiß, 1999).

Table 4.2: List of areas and sub-areas of biotechnology relevant for the equipment and supplies sector according to Reiß (1999)

B.4	**Industrial biotechnology: food/feed, paper, textile, and pharmaceutical and chemical production**
4.1	enzymatic processes
4.2	development of bioprocessing techniques (fermentation, immobilisation of biocatalysts, quality control etc.)
4.3	downstream processing
B.7	**Development of basic biotechnology**
7.1	techniques to determine the structure of biomolecules and study the structure-function relationship.
7.2	techniques to build biomolecules (nanotechnologies)
7.3	interaction of biomolecules with micro-electronic devices, incl. biosensors, biomonitoring
7.4	genome analysing techniques
7.5	bio-data-informatics (set of tools, which is applied to solve data handling and processing problems in biological research e. g. genome sequencing)
7.6	bio-informatics (application of biological principles of information processing for technical applications)

Source: Reiß (1999)

The three sub-areas enzyme processes (B 4.1), development of bioprocessing techniques (B 4.2), and downstream processing (B 4.3) of the application-oriented industrial biotechnology related to food and feed production, paper-, textile-, as well as pharmaceutical- and chemical production are no central issues of the programme 'Biotechnology 2000'. Nevertheless, these areas are publicly funded under the frame of the programme 'Research for Environment' (in responsibility of the BMBF and other ministries). Moreover, they might be topics of the research work supported by the AiF. Additionally, these sub-areas are obviously relevant for industrial application with respect to environmental friendly production processes. Accordingly, they are funded by the German Environment Foundation (Gießler and Reiß, 1999).

Public research promotion in area B7 has a strong focus on techniques to determine the structure of biomolecules and studies concerning the structure-function relationship (sub-area 7.1), as well as techniques to build biomolecules (sub-area 7.2). All in all, the study of Gießler and Reiß (1999) revealed that basic biotechnology is a very important area within the German biotechnology funding.

An estimate of biotechnology funding for areas B4 and B7 according to Gießler and Reiß (1999, cf. chapter 2.1 for details) is given in table 4.3. Accordingly, total funds devoted to research relevant to the equipment and supplies sector are estimated to about 403 million € during 1994-1998 (originating mainly from Biotechnology 2000).

Table 4.3: Rough estimates of money spent on funding areas B4 and B7 during 1994 and 1998

Programme/Activity	**Biotech budget 1994 - 1998 (million €) area B4**	**Biotech budget 1994 - 1998 (million €) area B7**
Biotechnology 2000: project funding (recorded)		283
AiF-Research (recorded)	52	
Total (recorded)	52	283
Total (interpolated)	62	341

Source: Gießler and Reiß, 1999; own calculations

4.1.4 Special programmes for university-industry research collaboration

There are no special programmes for research collaboration in this particular field. However, the Centre of Excellence for Bioprocessing in Stuttgart (affiliated to the FhG-IGB institute) which is funded by the BMBF, the German Environment Foundation, the German Research Association, the State of Baden-Württemberg, and the European Union, also has a special focus on industry collaborations. In addition, project funding within Biotechnology 2000 puts strong emphasis on joint industry-academic projects.

4.1.5 National Involvement in Framework (no.IV) programmes

There is no programme of the Fourth Framework which concentrates on equipment and supplies projects like in the two other sectors. All three biotechnology relevant programmes (BIOMED, FAIR and BIOTECHNOLOGY) should have some influence on the equipment and supplies area. Hence, to estimate the potential of funding we sum up the involvement of German researchers in any of the three programmes. This reveals that German researchers took part in 397 projects and co-ordinated 183 projects thereof. The funds granted to researchers in German institutions within the Biotechnology programme amounted to 216 million € (table 4.4).

Table 4.4: Involvement of German researchers in framework programme Biotechnology

Granted projects with German co-ordinator	Granted projects with German participation	Funds granted to German partners [MEuro]
183	397	216

Source: EU Querschnittskontaktstelle (1999)

4.2 Industrial structure

The survey

Via desk research, we have identified 210 companies which were potentially active in the equipment and supplies sector. In response to our survey, we have received

53 questionnaires back that were partially or fully completed. 5 % of the 210 firms answered that they actually did not apply to our sector definition, or were excluded because they were merely sales organisations of larger groups from abroad.

Table 4.5: Overview of the German equipment and supplies industry

Number of companies (extrapolated)	200
Number of employees (extrapolated)	8,400[11] (lower bound: 4,000[12])
Total turnover (extrapolated)	1,751 million € [13]
Total biotech turnover (extrapolated)	1,278 million €
Agencies funding research	BMBF, DFG, AiF, *Länder* ministries
Number of dedicated biotech institutes	13 (cf. table 4.1)
Number of master and PhD degrees awarded during 1994-1998	914 (cf. table 1.6) 165 (ibid.)
Regulatory authorities	Federal Ministry of Labour and Social Affairs (90/679/EWG), *Deutsches Institut für Normung e.V.* (German Institute for Standardisation, Berlin) *Berufsgenossenschaft der chemischen Industrie*, Heidelberg (professional/trade organisation of the chemical industry)
Regulations	*Gesetz zur Regelung der Gentechnik* (GenTG, genetic engineering act) BioStoffVerordnung (translation of 90/679/EWG) DIN standards

We thus estimated that there are around 200 companies in Germany which match our sector definition of the equipment and supplies sector (table 4.5). The actual number could be lower, because we assumed that the rate of companies not applying to our sector definition (5 %) remains the same within "respondents" and "non-respondents". On the other hand, the actual number of companies in this area could also be higher because we might have missed some companies when screening several databases. However, we consider the number of 200 companies in the German equipment and supplies sector as an upper bound. The numbers on employees (8,400) and industry turnover (1.8 billion in total, 1.3 billion in biotech) are based on this assumption and could therefore be biased upward as well. If the

11 Calculated by multiplying the number of companies in each category by the average number of employees in each category.

12 Calculated by multiplying the number of companies in each category by the lower boundary of employees in each category.

13 Total average turnover per company multiplied by 200 companies.

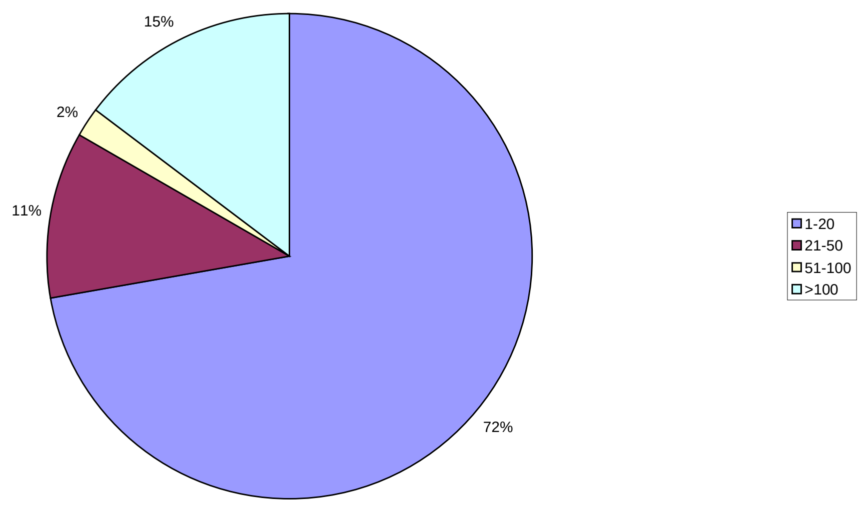
median is used rather than the average, total annual turnover amounts to 130 million €, and to 60 million € in biotech.

The sample

The following numbers refer to the sample of the 53 companies of the equipment and supplies sector from which valid questionnaires have been received.

The size distribution in terms of employees is shown in figure 4.1. Most of the firms (72 %) are small firms employing 1 to 20 individuals. 11 % of the firms employ between 21 and 50 people whilst only 2 % replied they would have 51 to 100 individuals on their pay-roll. 15 % of the companies have a workforce of more than 100 people.

Figure 4.1: Size distribution in terms of employees of the companies in the equipment and supplies sample



The majority of companies (71 %) were established independently. Only some companies (17 %) originated from other firms or were founded as a spin-off from PSR (12 %).

Around 56 % of the firms are older than five years, 43 % have been set up between 1994 and 1998. Around 40 % earned between 100.000 € and 1 million € total turnover in 1998. One fourth earned between 1 million € and 5 million €. There are 11 % very small companies (turnover below 50.000 €). 21 % of the firms in the sample earn more than 10 million € per year. The median of turnover of the equipment and supplies sample was 650,000 € in total and 300,000 € in biotech.

Almost 80 % of the companies achieve more than half of their total annual sales in biotechnology. Remarkable 57 % of the firms in the sample generate 100 % of their turnover in biotechnology.

By far the majority of the firms does have product sales in biotechnology (86 %). Almost half of the firms of the sample (46 %) sell their goods mainly in Germany. Europe emerged as a main market by 32 % of the firms, whereas merely 16 % of the firms see their main product market in the USA. Taking into account the fact that most of the patents (55 %) held by the firms of the sample have national claims only, it should be reasonable to assume that the majority of the equipment and supply firms looked at focus on the domestic market solely.
Unfortunately, we have only a few answers on the importance of licensing indicating that 9 % of the firms have licensing income. Due to the lack of data we had to discard a further analysis on this issue.

Only 55 % of the firms from this sector have reported of R&D collaborations either with organisations from PSR or with other companies. For both, collaborative R&D with PSR (75 %) as well as with companies (61 %), the partner for the firms in our sample is located in Germany. On average, the companies established 1.3 collaborations with both public and private domestic partners.

Hence, we have evidence to believe that the commercial as well as the scientific (technological) focus of the firms from the equipment and supplies sector is located in Germany.

BINGOs

There are no BINGOs dedicated particularly to the equipment and supplies sector as there are in the other two areas. However, the Association of German Biotechnology Companies (VBU; www.dechema.de/biotech/vbu.htm), the Association of the German Diagnostics Industry (VDGH; www.vdgh.de) and the German Association of Biotechnology Industries (DIB; www.vci.de/dib) do have some influence (cf. chapter 2.2 for further information on these organisations). We consider the VDGH important to the equipment and supplies industry although we have grouped diagnostics within the bio-pharmaceuticals area because this association has a broad focus and traditionally represents such kind of companies which should apply to both sector definitions.

4.3 Consumer attitudes and market demand

The equipment and supplies sector as such only exists according to our definition – there is no comparable statistical sector. Hence, there are no publicly available information about market size, growth rates etc. and it is further more difficult to make statements in general about the development of this sector. The industry is more concentrated than the pharmaceutical industry. R&D and sales expenses are relatively high and should be comparable to the pharmaceutical industry. We have assessed the possibility to investigate certain sub-sectors of this industry in depth, using systematic directories of statistics on production (PRODCOM, STAN) or balance of trade (ITCS). These attempts were doomed to fail because this would by far exceed the budget constraints faced in the EBIS project and the expected results might not be valuable after all. The VDGH publishes numbers on market size of the diagnostics sector, estimating the volume for diagnostics based on biotechnology in 1997 to 350 million € representing 30 % of the total domestic diagnostics market. Estimations of the size of the equipment and supplies market as a whole in Germany provided in diverse studies are in the order of magnitude of 1 billion € (for the year 2000; Becher and Schuppenhauer 1996, Becher 1997, Streck and Pieper 1997, which all refer to the same survey). This is based on the assumption that the turnover generated by the equipment and supplies firms is around 50 % of the turnover in related areas. We regard this as a relatively high number, taking into account that expenses on equipment and supplies in research centres (like the FhG- or MP-Institutes) do not exceed 30 % of the total budget on average. This share should normally be higher than in industry.

Business opportunities may not have been favourable between 1994 and 1998 as we would have otherwise seen more company foundations in this period (see above). Tight budgets of public customers (e. g. public health care organisations, hospitals) impeded a promising business development.

We argue that mainly the big suppliers could take advantage of opportunities offered by customers from other industries, because they have the potential to establish own standards and offer product lines for several purposes. Standardisation and certification is a major issue for equipment and supplies products. We have identified around 500 standards defined by the *Deutsches Institut für Normung e.V.* (German Institute for Standardisation) with potential impact on product and technology development at companies. Customers from industry often stick to one or just a few suppliers which they trust both in terms of quality and timeliness. Smaller suppliers might often have technologically superior products but lack in reputation and marketing efforts impeding their business development. Thus they frequently focus on niche markets where they can be successful in terms of market share but where turnover potential should be limited.

The importance of biotechnology among technology policy makers in Germany was increasing during the 1990s. In addition to a number of publicly supported research organisations directly concerned with research on and development of equipment and supplies, money spend for institutions related to other biotechnology sectors provided further demand for equipment products. We estimate that up to 30 % of the total budget of an institute concerned with research in biotechnology is spend for supplies and for furnishing and maintaining of its laboratories. This ratio should also apply for publicly funded research programmes, thus representing a considerable factor for the total demand potential of the equipment and supplies sector. This is the most obvious effect of public procurement programmes in this sector. As an indirect effect of technology policy, the infrastructure for R&D is established and maintained. One example are the sequencing efforts concerning the human (German Human Genome Project, DHGP) and the plant genome (GABI, *Genomanalyse im biotechnologischen System Pflanze*). The former is currently funded with 20 million € per year by the federal government. Research on the plant genome is supported by 1.5 million € to 3 million € per year.

It is not realistic to point to one particular directive which would affect the equipment and supplies sector as a whole. Many regulations influence the development of the industry which also apply to non-biotech companies. Compared to the other two fields (bio-pharmaceuticals and agro-food) the equipment and supplies industry is merely moderately affected by the numerous laws and guidelines in Germany. Hence, the laws discussed in chapters 2.1 and 3.1 influence the development of the sector indirectly, because they might impede the business opportunities of the customers of the equipment and supplies industry. On the other hand, certain regulations might also be the foundation of the business of many companies of this industry. One example would be firms which sell equipment to detect GMOs in food or the environment. Their business is actually mainly based on the EC directives 219 and 220 and on the public awareness against GMO contamination, respectively.

Social Acceptance in the Equipment and Supplies Sector

There are no specific information or surveys available concerning the attitudes and public perception of bioinstruments in Germany. Since gene test activities are closely related to the field of bioinstruments (at least when regarding the "material" basis of such tests) a short overview is given in the following concerning the public debate on gene tests in Germany.

Due to international sequencing projects such as the Human Genome Project increasing genetic information is internationally available which can be used for different purposes. One of the first application area of these information are genetic tests which can be used for different purposes with a focus in the medical field. While genetic tests offer new diagnostic opportunities (e. g. identification of new pathogens, efficiency of the tests), fears arise about their legal, political social and ethical consequences. Therefore, an expert-based debate on the application of gene tests and its impacts has been carried out in Germany since the beginning of the 90s. However, up to now there are no participatice technology assessment or structured social debate activities concerning genetic testing in Germany on which lay people have participated. All technology assessment activities in this field are more or less based on expert estimations of different fields and disciplines.

In 1993 the Office of Technology Assessment of the German Parliament (TAB) conducted a study on Genetic Mapping – Opportunities and risks of genetic diagnostics. It was a classical expert based Technology Assessment and recommended legal rules in fields such as criminal justice, health and life insurance, employees and work places and the health care system (Hennen et al. 1993). However, the recommendations have not been followed by legislative decisions so far. In addition, a monitoring process on gene therapy has been set up (Gloede 1997). Especially the opportunities of DNA chips in the diagnostic field are analysed in this still running project. Furthermore, it is planned to give the view of lay people more weight in the debate. However, the attempt to organize the first Consensus Conference in Germany in relation to gene tests failed due to missing political support.

Besides the activities of TAB, additional technology assessment studies have been carried concerning genetic testing. These include a study of the Biomedical Innovation Company, Bad Oeynhausen, in which the scientific perspective of gene diagnostics and its economic, social and legal impacts have been analysed mainly with the help of expert interviews (Paslack und Blanke 1997). In addition, a research group on bioethics just finished a study on the implications of the preimplantation diagnostic (Kollek 2000).

4.4 Prospects for the sector

Due to the high uncertainty and doubtful reliability of quantitative figures on market data in this case we found it appropriate to merely present qualitative assessments regarding the future expectations of this sector. Our considerations are based on reflections of the expected development of the business of the customers of the equipment and supplies companies as well as trends in public procurement programmes. Regarding the latter an important trend on the technology policy side with relevance to the equipment and supplies is that the research area B7, development of basic biotechnologies, should be strengthened in future (Gießler and Reiß 1999). Additionally, the sector will benefit from plans to rise funding for research on the (human and plant) genome. The scientific community claims to increase the current resources at least tenfold if Germany wants to pick up with its

competitors from the US, the UK, and continental Europe. Policy already signalled consent in the necessity to become more competitive, but a decision might not be taken before mid 2000 (Nature 1999). In case the BMBF concludes to increase funding, this will also boost demand for equipment and supplies products as their share of total expenses is normally rather high in sequencing (up to 50 %). Future prospects also depend on the performance of the programme to analyse the plant genome (GABI). It started in late 1998 and has a duration of eight years. The aims are to support basic research on arabidopsis, barley and other crops (step 1), and applied research in companies (step 2) to exploit the results of the first step.
It is likely that research policy will emphasise genome sequencing and the exploitation and application of the information gained therewith in future. This will positively influence the development of the equipment and supplies as well, whereby we expect a certain shift of attention from structural to functional genomics approaches. This tendency will have impact on the types of equipment demanded.

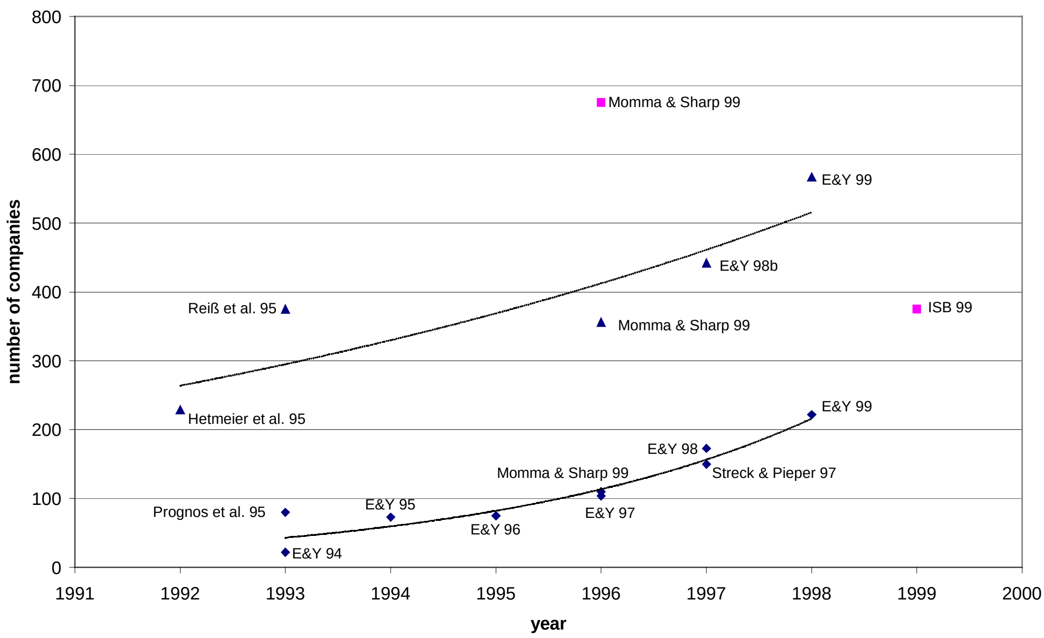
The customers of the companies in the equipment and supplies sector are mainly
a) hospitals,
b) physicians,
c) the biotechnology industry,
d) the pharmaceutical industry,
e) the agro-food industry,
f) the fine chemical industry.

Hospitals and practices face cost containment pressure. Due to the strict employment laws in Germany and the high unemployment rate it is unlikely that this pressure can be reduced by decreasing personnel cost. It is henceforth arguable that they might try and safe money spent for equipment. This particularly applies for larger investments of 500,000 € and above. Thus, it should only be possible to increase the turnover from sales to those institutions by replacing conventional equipment and supplies products. Taking all this into account, we estimate flat growth rates for the business with customer groups a) and b).

Growth is more likely to come from the business to business field (customers c to f). The biotechnology industry as a whole experienced a steep rise in Germany during the 1990s (figure 4.2). Many new companies have been established providing a high demand potential on the one hand, but often facing budget constraints on the other hand so that the actual buying power might not be all too high. Growth rates are nevertheless appealing for this industry.

The pharmaceutical industry in Germany is strong in terms of domestic sales but relatively weak compared to international competitors mainly from the UK and the US and the business is stagnating if at all. The R&D units of the pharmaceutical firms should nevertheless be the most important customers for the equipment and supplies sector in terms of total turnover generated from industry. Future growth in turnover from this industry will again depend on the ability of the equipment and supplies companies to replace conventional products and keep up with the needs of their customers. The firms investigated in our study are likely to succeed in this as they meet the requirements of modern approaches pursued in pharmaceutical R&D. We expect over-proportional growth rates in the equipment and supplies sector relative to the pharmaceutical industry in mid-term because more and more companies (have to) introduce modern biotechnological approaches in their R&D efforts.

Figure 4.2: German biotech companies 1992-1999



source: Wörner and Reiss (1999)

Although biotechnologically derived agro-food products lack in consumer acceptance, equipment like bio-reactors, separation technologies or cell technology and supplies like bacteria, yeast or industrial enzymes are used in both production and R&D. As most of these tools are already introduced as standard equipment of laboratories and plants respectively, we do not expect exceptionally high growth rates from this area. Growth might be more likely to arise by sales of detection systems for GMO contaminated material.

The chemical industry uses supplies like industrial enzymes in a wide variety of areas. It has been predicted that the global market will have 6.5 % growth rate per annum. The industrial enzyme sector is an example of the seamless transition from traditional biochemical methods to the use of genetic engineering and recombinant production. German companies only operate in niche sectors of the enzyme market but hold significant shares in them.

We argue that the market of the equipment and supplies sector is stable and robust because its products are used in a number of industries and by several institutions. However, we do not consider this business as a growth industry (such as the bio-pharmaceutical or the IT sector) in general. We conclude that future prospects will mainly depend on replacing conventional technologies and setting and meeting of standards across industries.

5. Comparing the Three Sectors

Table 5.1 summarises key indicators of the knowledge and skills network of the German EBIS-sectors. Both the bio-pharmaceutical and the agro-food sector are supported by (quantitatively) strong human resources. The human resource for the equipment and supplies sector seems to be far lower. To some extent this could reflect the methodological problems of delimiting relevant courses (cf. chapter 1.3). However, there should be at least three other reasons explaining this. Firstly, the science base in equipment and supplies is less clearly definable because a number of qualifications is required in this broad area (e. g. in chemical engineering, mechanical engineering, biology, physics, etc.). Secondly, qualifications needed in this sector are more technical skills as the firms are more involved in the development of products or technologies rather than (basic) product research (nearly 86 % of the firms in the sample conduct development of either products or technologies rather than product research). Thirdly, we believe the considerably lower numbers of students and graduates in the equipment sector are also due to the unfavourable development of the job market in the chemical industry in the 1990s. The number of students in this field declined steadily in Germany over the years. Hence, less graduates were available to the biotech firms as well.

Regarding funding, the dominance of the bio-pharmaceutical area becomes apparent. Public spending in this sector was four to five times higher between 1994 and 1998 than in both the agro-food and the equipment and supplies field. The BMBF and the DFG seem to be the most important funding organisations. Due to the fact that each of the three sectors benefited from the BioRegio efforts, we consider the over all effect of special programmes to stimulate links of research and industry as rather high. German participation in EU-programmes was high in the bio-pharmaceutical area compared to the agro-food sector. This, together with the high spending of domestic funding organisations, should underpin the impression that bio-pharmaceutical research has been the main focus of the German (bio-) technology policy, whereas the agro-food sector is lacking behind. To estimate the participation of German researchers in EU-projects related to the equipment and supplies sector, we added up the respective numbers of the programmes BIOMED, FAIR and BIOTECHNOLOGY of the fourth framework programme, because all three programmes are relevant to this sector while it is not possible do delimit certain parts of these programmes which actually represent research in equipment and supplies.

Table 5.1: Summary of Key Indicators of the Knowledge/Skills-Networks in Germany by Sector

ELEMENT	Biopharms	Agro-food	Equipt/ Supplies	Global*
1. Science Base				
1.1 Human resources *(low/medium/high)*	**High**	**High**	**Medium**	**High**
1.2 Funds: (total in EUROs)	**1,710**	**319**	**403**	**2,432**
% GERD	**0,82 %**	**0,15 %**	**0,19 %**	**1,16 %**
1.3 Funding organisations *(names)*				
Ministries	BMBF,BMG	BMBF,BML	BMBF	**BMBF**
Agencies	DFG, AiF	DFG	DFG, AiF	**DFG**
Charities	Stifterverband			
1.4 Significance of special programmes in stimulating research/industry links *(low/medium/high)*	**High**	**Medium**	**High**	**High**
1.5 EU programmes				
- No. projects as coordinator	**68**	**52**	**183**	**183**
- No. projects as partner	**138**	**110**	**397**	**397**

Table 5.2 summarises key indicators of the industry and supply network of the German EBIS-sectors. Most of the firms in the German universe were bio-pharmaceutical companies (48 %), just ahead of the equipment and supplies firms (41 %) and the agro-food companies (11 %) well behind. Both the bio-pharmaceutical as well as the equipment and supplies companies are quite young enterprises. 60 % of the bio-pharmaceutical firms of the sample were founded between 1994 and 1998 – 32 % are not older than two years. 43 % of the equipment and supplies entities had their year of foundation between 1994 and 1998. The difference to the agro-food sector becomes obvious by the fact that 44 % of the agro-food companies have been founded before 1990 whilst only 25 % have been established between 1994 and 1998.

Table 5.2: Summary of Key Indicators of the Industry/Supply Networks in Germany by Sector

ELEMENT	Biopharms	Agro-food	Equipt/ Supplies	Global*
2. Industrial Structure				
2.1 Population of firms				
- No. firms (total identified)	**242**	**56**	**210**	**508**
- No. responding firms	**70**	**20**	**53**	**143**
2.2 No. existing firms founded 1994-98 (estimated)	**145**	**14**	**86**	**245**
2.3 Significance of multinationals				
- Domestic *(i.e with national HQ)*	**medium**	**low**	**high**	**medium**
- Foreign-owned	**medium**	**low**	**high**	**medium**
2.4 Size distribution of firms (%): 1-20	**55 %**	**32 %**	**72 %**	**57 %**
21-50	**28 %**	**26 %**	**11 %**	**21 %**
51-100	**9 %**	**26 %**	**2 %**	**9 %**
>100	**9 %**	**16 %**	**15 %**	**12 %**
2.5 Turnover of dedicated bt-firms *(100% turnover in biotechnology)*				
- *Average*	**1.900.000**	**n.a.**	**12.500.000**	**n.a.**
- *Median*	**150.000**	**n.a.**	**933.000**	**n.a.**
- *% of responding firms reporting turnover*	**54%**	**60%**	**68%**	**60%**
2.6 Location of main PSR collaborators *(domestic/EU/US)*	**domestic**	**domestic**	**domestic**	**domestic**
2.7 Location of main firm collaborators *(domestic/EU/US)*	**domestic**	**domestic**	**domestic**	**domestic**
2.8 Significance of BINGOS *(low/medium/high)*	**high**	**high**	**medium**	**high**

MNCs like Bayer, Schering, BASF, Aventis, and Novartis, Roche, SmithKline Beecham, Amgen, Glaxo Wellcome are of course active in Germany but the pharmaceutical market is rather fragmented so that there are many niches for smaller players. Besides, the scientific development in biotechnology is fast enough that even smaller firms can challenge the bigger firms. However, MNCs are certainly important for the small and medium sized bio-pharmaceutical enterprises, e. g. as a co-operation partner or as a customer.

The agro-food industry in Germany is even more fragmented. Agrevo, KWS, Novartis Seeds and Monsanto are active in the agro-business, Nestlé and Novartis Nutrition are of significance in the food area. In particular, the more innovative companies often are MNCs. Both the utilisation of genomics as well as the development of functional food is mainly driven by more established, multinational food companies.

The equipment and supplies business is more concentrated than both of the other sectors. Many of the customers rely on the reputation and the standards of the established firms rather than cost advantages of the younger players. The German equipment and supplies sector can be broadly divided in (mostly domestic) SME and (mostly international) MNCs. The sample more or less characterises the SME. The multinationals are clearly underrepresented in our sample because many of them merely have sales organisations in Germany and no research facilities or, their lines of business matching the EBIS sector definition could not be clearly delimited. We would like to analyse this development block of domestic, young SME and the MNC, like Roche Diagnostics, Abbott, Bayer, Johnson&Johnson, Beckman Coulter, Dade Behring and Becton Dickinson which rule the (diagnostics) business, in the equipment and supplies sector case study. However, there are business opportunities for niche players in the supply sector concerning substances for special applications (with low market volumes).

We consider the significance of BINGOs as medium to high for the three sectors because the biotechnology industry is a young sector and may be in need of lobbying activities against more established branches or of representing the requirements of young technology firms against federal and local authorities.

Whereas the significance of PINGOs for the bio-pharmaceutical companies should not be high and is clearly negligible for the equipment and supplies firms they are highly important in the agro-food sector. In particular, the activities of Greenpeace and the consumer organisations (cf. chapter 3.3) are of great influence to the development of the agro-food industry.

Table 5.3 summarises key indicators of the demand and social acceptability networks in the German EBIS sectors. There are no prominent regulations (except of the Genetic Engineering Act) directly affecting the business of the equipment and supplies firms. However, many standards and less comprehensive (but numerous) regulations do influence (and possibly hamper) the business prospects of the equipment and supplies companies.

Table 5.3: Summary of Key Indicators of Demand/Social Acceptability Networks, by Sector

ELEMENT	Bio-pharms	Agro/ Food	Equipt/ Supplies	Global
3. Demand/Public Acceptability				
3.1 acceptance of biotech products/technologies *(high/medium/low)*	**High**	**Low**	**High**	**Medium**
3.2 Regulation: more restrictive than EU? *(yes/no)*	**No**	**No**	**No**	**No**
3.3 Influence of PINGOs on public acceptance *(high/medium/low)*	**Low**	**High**	**Low**	**Medium**

As an attempt to explain the evolution and current state of an industry we propose to use the theoretic concept of the "development block" introduced in the paper on technological systems. We show how this framework could be applied in the German agro-food sector exemplary.

The modern biotechnological paradigm induced structural tension leading to disequilibrias. This usually goes in line with the entrance of new competitors. However, in the agro-food sector it was more the established firms that gave way to the pressure of new production technologies and therefore tried to adapt and adjust to new conditions. We argue that the majority of the agro-food companies in Germany sees themselves as being forced to change rather than having the opportunity to exploit business opportunities. The transformation towards a development block is normally supported by a sequence of complementarities. Its three main prerequisites are

a) Economic competence
b) Critical mass and
c) Institutional infrastructure

According to the low number of agro-food firms in Germany and the low pervasiveness of biotechnology in this sector, we find that the agro-food sector has not yet managed to become a prospering development block. What may be the reasons for this?

The agro-food sector is mainly characterised by relatively old, middle sized companies, especially in the production of seeds. These firms may have a deficit in economic competence (EC), their internal structures may not be appropriate to follow the path of change management. Taking the high number of graduates and PhDs granted in the agro-food area in Germany between 1994 and 1998 into account, one could assume on first sight that it should be easy for the companies to allocate new agents with the desired economic and scientific competence. However, as this is obviously not the case, it seems that the academic system in the German agro-food sector does not train the students according to the requirements of the job market and that the numerous agronomic research organisations are at least not properly linked to the private enterprises. Hence, the institutional infrastructure and the direction of public funding in the agro-food sector seems to offer opportunities for improvement. The problems should be typical for mechanisms with negative impact often observed in weak development blocks: increase in static instead of dynamic efficiency (in the German case: a broad science base, indicated by the number of students in relevant fields, but not targeted to the needs of and not linked with the companies) and individual interests competing with public interests (subsidy and insurance schemes in the German agro-food sector). Critical mass should not be a hampering factor due to the size of the German food market and the international agro market.

The results of the statistical analysis of the German sample indicates a prevalence of the NSI. However, this is just the average figure. Taking into account that virtually all of the successful companies are linked to international partners and not bound to national borders (particularly in the bio-pharmaceutical area), we propose to distinguish between the occurrence of a certain type of innovation system (either national or sectoral), which could be due to historical circumstances, and a framework that should likely lead to a prospering industry. In some cases, both could be identical, but for others we may identify the need for a transformation process. This should be an issue in the sectoral case studies.

6. References

Advisory Board for Technology, Research and Innovation (1997): Biotechnologie, Gentechnik und wirtschaftliche Innovation. Bonn: BMBF

Akademie für Technikfolgenabschätzung in Baden-Württemberg (Ed.) (1995): Bürgergutachten: "Biotechnologie/Gentechnik - Eine Chance für die Zukunft?", Stuttgart: Akademie für Technikfolgenabschätzung

Ammon, U. (1998): Dialog und Diskurs – Wo stehen wir und wie können wir weitermachen? Befunde und Schlußfolgerungen für TA-Verfahren. In: Ammon, U.; Behrens, M. (Eds.): Dialogische Technikfolgenabschätzung in der Gentechnik: Bewertung von ausgewählten Diskurs- und Beteiligungsverfahren. Dokumentation einer Tagung der Sozialforschungsstelle Dortmund und der FernUniversität Hagen am 26.11.1996. Münster: Lit-Verlag 1998, 134-143

Arbeitsgemeinschaft industrieller Forschungsvereinigungen "Otto von Guericke" e.V. (AiF) (1997): Forschungsreport 1997. Köln: AiF

ASSINSEL (1999): World seed statistics. http://www.worldseed.org./~assinsel/

Assouline, G.; Joly, P.-B. (1999): The biotechnology policy making and research system in the different countries: convergencies and specifics. In: Enzing, C.M. et al. (Eds.): Inventory and analysis of biotech programmes and related activities in all countries participating in the Biotechnology Programme 1994-1998. Analytical report. Delft 1999, p. 8-24

Bassermann, K. (1998): Der Markt für Pflanzenschutzmittel. Konzentrationen und Kooperationen der Branchenteilnehmer. Agrar-Wirtschaft 47, 11, 419-423

BBA (2000): BioSearch: Gentechnik-Datenbank der Biologischen Bundesanstalt für Land- und Forstwirtschaft (BBA). www.bba.de/tentech/gensight.htm

Becher; Gehring; Lang; Schmoch, U. (1996): Patentwesen an Hochschulen. Bonn: BMBF

Behrens, M.; Meyer-Stumborg, S.; Simonis, G. (1997): Von den Nachbarn lernen? Die deutsche Nahrungsmittelindustrie im gesellschaftlichen Konflikt um die Einführung der Gentechnik. In: Martinsen, R. (Ed.): Politik und Biotechnologie. Baden-Baden 1997, 257-279

Biehl, B. (1999): Wettbewerbsstrukturen. Konzentration als Konstante. Lebensmittelzeitung 40/1999, 81

BMBF (1996): Bundesbericht Forschung 1996. Bonn: Bonner Universitäts-Buchdruckerei

BMBF (1997b): Leitprojekt "Diagnose und Therapie mit den Mitteln der Molekularen Medizin". Pressedokumentation zum Ideenwettbewerb. Bonn: BMBF

BMBF (1999): Facts and Figures 1998. Bonn: Federal Ministry of Education and Research

BMFT (1993): Health Research 2000 - Programme of the German Federal Government. Bonn: BMBF

BML (1996): Nachwachsende Rohstoffe. Bonn: BML Referat Öffentlichkeitsarbeit

Bundesministerium für Ernährung, Landwirtschaft und Forsten (ed.): Statistisches Jahrbuch für Ernährung, Landwirtschaft und Forsten der Bundesrepublik Deutschland 1998. Münster: Landwirtschaftsverlag GmbH, 1999

Bundesverband der Pharmazeutischen Industrie e.V. (BPI) (1999): Pharma Daten 99. Frankfurt

CheManager (1999a): Patente und Pipelines. Die Risiken im globalen Pharmageschäft. CheManager 9/1999, 12

CheManager (1999b): Pharmaforschung. Kosten - Kooperationen - Synergien. CheManager 11/1999, 13

CheManager (1999c): Gentechnik schafft neue Arzneimittel. CheManager 11/1999, 13

Christensen, J. L.; Rama, R.; von Tunzelmann, M. (1996): Innovation in the European food products and beverages industry. Industry studies of innovation using C.I.S. data. Study on behalf of the Eurpean Commission, DG XIII, EIMS Publication No. 35

Dally, A. (Ed.) (1997): Gentechnologie in Niedersachsen. Ergebnisse eines Diskursprojektes. Band 1: Berichte. Rehburg-Loccum: Evangelische Akademie Loccum

DECHEMA (2000): Gentechnisch hergestellte Medikamente. Rekombinante Arzneimittelwirkstoffe und Impfstoffe in Deutschland und ihre Umsätze. http://www.dechema.de/deutsch/isb/wirkst.htm (Version April 3rd, 2000)

Enzing, C.M. (1999): Implementation of biotechnology policies. In: Enzing, C.M. et al. (Eds.): Inventory and analysis of biotech programmes and related activities in all countries participating in the Biotechnology Programme 1994-1998. Analytical report. Delft 1999, p. 25-39

Enzing, C.M. et al.(1999): Inventory and analysis of biotech programmes and related activities in all countries participating in the Biotechnology Programme 1994-1998. Analytical report. Delft 1999

Ernst&Young (1998): European Life Sciences 1998.

EU Querschnittskontaktstelle (1999): Umfrage 1998. Unpublished survey. Bonn

European Commission: The Europeans and modern biotechnology. Eurobarometer 46.1. Directorate General XII Science, Research and Development: Biotechnology. Luxembourg: Office for official publications of the European Communities 1997

European Commission: Panorama of EU industry 95/96. Luxembourg: Office of Offical Publication of the EU, 1996

European Commission: The Europeans and modern biotechnology. Eurobarometer 46.1. Directorate General XII Science, Research and Development: Biotechnology. Luxembourg: Office for official publications of the European Communities 1997

European Venture Capital Association (EVCA): diverse EVCA yearbooks. Zaventem

Federal Statistical Office Germany (1995): Ausgaben für biotechnologische Forschung. Stuttgart

Federal Statistical Office Germany (1998): Statistisches Jahrbuch 1998. Wiesbaden

Federal Statistical Office Germany (1999): Statistics on students and examinations (ordered information). Wiesbaden

Federal/Länder Commission for Educational Planning and Research Promotion (BLK) (1997): Förderung von Erfindungen und Patenten im Forschungsbereich. Heft 56. Bonn

FNR - Agency for Renewable Resources (1998): written information. FNR, Gülzow

Gaycken, U. (1998): Kuratorium Gentechnik in der Pflanzenzüchtung. In: Ammon, U.; Behrens, M. (Eds.): Dialogische Technikfolgenabschätzung in der Gentechnik: Bewertung von ausgewählten Diskurs- und Beteiligungsverfahren. Dokumentation einer Tagung der Sozialforschungsstelle Dortmund und der FernUniversität Hagen am 26.11.1996. Münster: Lit-Verlag 1998, 72-75

Gießler, S., Reiß, T. (1999): Inventory and analysis of biotech programmes and related activities in all countries participating in the Biotechnology Programme 1994-1998. National Report of Germany. Karlsruhe 1999

Gloede, F. (1997): Technology Assessment of gene therapies in Germany. Baltimore: Johns Hopkins Oncology Center

Grupp, H.; Hinze, S.; Reiß, T.; Schmoch, U.: Technologische Position Deutschlands im internationalen Wettbewerb. Karlsruhe: Fraunhofer Institute for Systems and Innovation Research, 1997

Hampel, J.; Ruhrmann, G.; Kohring, M.; Goerke, A. (1998): Germany. In: Durant, J.; Bauer, M. W.; Gaskell, G. (Eds.): Biotechnology in the Public Sphere. A European Sourcebook. London: Science Museum 63-76

Hampel, J.; Keck, G.; Peters, H. P.; Pfennig, U.; Renn, O.; Ruhrmann, G.; Schenk, M.; Schütz, H.; Sonje, D.; Stegat, B.; Urban, D.; Wiedemann, P. M.; Zwick, M. M.: Einstellungen zur Gentechnik. Tabellenband zum Biotech-Survey des Forschungsverbunds "Chancen und Risiken der Gentechnik aus der Sicht der Öffentlichkeit". Stuttgart: Akademie für Technikfolgenabschätzung in Baden-Württemberg. Nr. 87/1997

Hampel, J., Keck, G., Peters, H. P., Pfennig, U., Renn, O., Ruhrmann, G., Schenk, M., Schütz, H., Sonje, D., Stegat, B., Urban, D., Wiedemann, P.M., Zwick, M. M. (1997): Einstellungen der Gentechnik. Tabellenband zum Biotech-Survey des Forschungsbundes "Chancen und Risiken der Gentechnik aus Sicht der Öffentlichkeit". Akademie für Technikfolgenabschätzung in Baden-Württemberg. Nr 87/1997, Stuttgart

Hennen, L.; Petermann; T.; Schmitt, J. J. (1993): TA-Projekt "Genomanalyse" – Chancen und Risiken genetischer Diagnostik. Bonn: Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag

Hilliam, M. (1999): Functional Foods. The World of Ingredients, No. 3/4, 46-49

Hüsing, B.; Jaeckel, G.; Marscheider-Weidemann, F.: Potentiale und Entwicklungen im Bereich der Katalysatoren und Enzymtechnik. Karlsruhe: Fraunhofer Institute for Systems and Innovation Research, 1997

Hüsing, B.; Menrad, K.; Menrad, M.; Scheef, G.: Functional Food – Funktionelle Lebensmittel. Berlin: Office for Technology Assessment of the German Parliamanent, 1999

James, C. (1999): Global status of commercialized transgenic crops 1999. ISAAA Briefs No. 12: Preview, Ithaca (New York): International Service for the Acquisition of Agri-biotech (ISAAA)

Jany, K.-D., Greiner, R.: Gentechnik und Lebensmittel. Karlsruhe: Bundesforschungsanstalt für Lebensmittel, 1998 (BfE-R-98-1)

Jungmittag, A.; Reger, G.; Reiß, T. (2000): Changing innovation in the pharmaceutical industry. Springer, Berlin

Kochte-Clemens, B.; v. Schell, T. (1995): Werkstattgespräch "Nachwachsende Rohstoffe und moderne Biotechnologie". Diskursbericht. Stuttgart: Akademie für Technikfolgenabschätzung in Baden-Württemberg

Kollek, R.: Präimplantationsdiagnostik. Embryonenselektion, weibliche Autonomie und Recht. Tübingen: Francke-Verlag 2000

Kornobis, K.-J. (1999): Das siebte fette Jahr hat angefangen. Lebensmittelzeitung 17/1999, 74-75

Koschatzky, K.; Maßfeller, S.: Gentechnik für Lebensmittel? Möglichkeiten, Risiken und Akzeptanz gentechnischer Entwicklungen. Köln: Verlag TÜV Rheinland, 1994

Kutter, S. (1998): Essen der Zukunft: Heilsames Prinzip. Wirtschaftswoche, 3/98, 46-50

Leatherhead (1998): Fair winds or foul for Functional Foods? (http://www.lfra.co.uk/lfra/press673.htm)

Menrad, K. (1998): Consumer attitudes of modern biotechnology in the Agro-Food sector. In: Gaukel, V., Spiess, W. E. L. (Eds.): European Research towards safer and better food. Proceedings Par 1.3rd Karlsruhe Nutrition Symposium, 18-20. Oktober 1998. 329–339

Menrad, K. et al. (1999): Future impacts of biotechnology on agriculture, food production and food processing – a Delphi survey. Phyisca. Heidelberg

Menrad, K., Kulicke, M., Lohner, M., Reiß, T. (1999): Probleme junger, kleiner und mittelständischer Biotechnologieunternehmen. Fraunhofer IRB Verlag. Stuttgart

Menrad, K.; Agrafiotis, D.; Enzing, C.; Lemkow, L.; Terragni, F.: Future impacts of biotechnology on agriculture, food production and food processing. Heidelberg: Physica-Verlag, 1999

Mühlenberg, K. (1997): Betreten verboten – keine Gefahr. Globus 4 – 5/97, 27-29

Müller, A. (1995): Werkstattgespräch " Neuartige Lebensmittel - Wie soll die Vermarktung reguliert werden ?" Diskursbericht. Stuttgart: Akademie für Technikfolgenabschätzung in Baden-Württemberg

Nature (1999): Germany drags its feet over demand for genome funds. Vol. 402, no. 16, p.706

OECD (1998): Main science and technology indicators – 1998/1. Bruxelles.

Paslack, R.; Blanke, M. (1997): Gendiagnostik zwischen Forschung und Markt. Bad Oeynhausen: GBM - Gesellschaft für Innovation und Technologietransfer Biomedizin mbH

Petermann, T.; Sauter, A.: TA-Monitoring "Xenotransplantation". Arbeitsbericht Nr. 4. Berlin: Büro für Technikfolgen-Abschätzung beim Deutschen Bundestag 1999

RAFI (1998): The world's top 10 seed corporations. http://www.rafi.org

Reiß, T. (1999): Results of biotechnology policies - biotechnology areas. In Enzing, C.M. et al. (1999). p. 50-61

Rieder, B. (1999): Meinungsklima Bio & Gentechnologie. Dramatische Polarisierung. Europa Chemie 12, 4–6

Riewenherm, S. (1994): Freisetzungen allerorten... GID 96/97, 11-13

Robert Koch Institute (1999): http://www.rki.de/gentec./ (different sheets related to field trials with GMOs and approved products)

Ronke, C.; Konrad, J. (1999): Handel sieht Wachstum in sensiblen Segmenten. Lebensmittelzeitung 17/99, 73

Saretzki, T. (1998): Das Diskursprojekt "Gentechnologie in Niedersachsen": Ein dezentralisiertes Forum für die Kontroverse zwischen "Machern" und "Mahnern" und seine Vermittlungsprobleme. In: Ammon, U.; Behrens, M. (Eds.): Dialogische Technikfolgenabschätzung in der Gentechnik: Bewertung von ausgewählten Diskurs- und Beteiligungsverfahren. Dokumentation einer Tagung der Sozialforschungsstelle Dortmund und der FernUniversität Hagen am 26.11.1996. Münster: Lit-Verlag 1998, 79-94

Schmoch, U., Norman Abramson, H., Encarnacao, J. (1997): Technology Transfer Systems in the United States and Germany. National Academy Press, Washington, D.C

Schwabe, U.; Paffrath, D.: Arzneiverordnungsreport 1998. Berlin, Heidelberg, New York: Springer-Verlag 1999

Senker, J. (1999): Policy instruments for technology transfer. In: Enzing, C.M., et al.: Inventory and analysis of biotech programmes and related activities in all countries participating in the Biotechnology Programme 1994-1998. Analytical report. Delft 1999. P. 40-47

Statistisches Bundesamt (1998): Statistisches Jahrbuch 1998. Wiesbaden

Statistisches Bundesamt: Fachserie 4: Produzierendes Gewerbe. Wiesbaden, 1999

Staudt, E., Kottmann, M., Krause, M. (1999): Kompetent zur Innovation? BIOforum 4/99. 165-168

Strodthoff, H. (1995a): Erfolgreiche Proteste. GID 106, 17

Strodthoff, H. (1995b): Rasanter Anstieg. GID 101, 10-12

Van den Daele, W. (1994): Das falsche Signal zur falschen Zeit. Politische Ökologie 35, 65, Special

Verband forschender Arzneimittelhersteller e.V. (VFA) (1999a): Statistics 99. Die Arzneimittelindustrie in Deutschland. Bonn

Verband forschender Arzneimittelhersteller e.V. (VFA) (1999b): Zulassungen für gentechnisch hergestellte Arzneimittel. Personal information dated September 2nd, 1999

von Schlotheim-Schottelius, B. (1997): Pflanzenschutz und Düngemittel. Exporte brachten Schwung ins Geschäft. Europa Chemie 12/97, 5

Warmuth, E. (1991): Biotechnology 2000: a new German R&D programme. Research Evaluation, vol. 1, no. 2, pages 77-88

WBA Institut für Marktforschung und Marketingberatung (1996): Gentechnik bei Lebensmitteln. Repräsentativbefragung im Auftrag des Gen-Dialogs. Hamburg

Wörner, S., Reiss, T. (1999): Arbeitspapier zum Bericht des Fachdialogs "Beschäftigungspotentiale der Bio- und Gentechnologie" im Bündnis für Arbeit. Fraunhofer ISI, Karlsruhe

Zentrum für Europäische Wirtschaftsforschung Mannheim ZEW, Deutsches Institut für Wirtschaftsforschung Berlin DIW, Fraunhofer Institut Systemtechnik und Innovationsforschung Karlsruhe ISI, Niedersächsisches Institut für Wirtschaftsforschung Hannover NIW, Stifterverband für die Deutsche Wissenschaft Essen WSV, Wissenschaftszentrum für Sozialforschung Berlin WZB (1999): Zur technologischen Leistungsfähigkeit Deutschlands – zusammenfassender Endbericht 1998. BMBF. Bonn