Bernhard Zechendorf

is a scientific documentalist working at the European Commission in the Directorate-General for Research. He is the founder and manager of a documentation service in the life sciences, and author of a series of articles in various fields of biotechnology as well as the editor of the *Inventory*.

**Keywords:** biotechnology policy assessment, public opinion, innovation, France, Germany, United Kingdom

Bernhard Zechendorf DG Research, European Commission, B-1049 Brussels, Belgium

Tel: +32 2 295 7910 Fax: +32 2 299 7860 E-mail: bernhard.zechendorf@cec.eu.int

# Biotechnology policy in European countries: An assessment

Bernhard Zechendorf Date received (in revised form): 12th March, 2004

#### Abstract

For more than 20 years, all major European governments have put biotechnology as a priority on their innovation policy agendas. How did each of the three big countries – France, the UK and Germany – manage their biotechnology policy, and what results have they achieved? A project funded by the European Commission tried to find out by assessing, over the period 1994–2001, the development of the knowledge base, patent activities, technology transfer measures, regulatory policy, industry promotion measure and public opinion. By adding data from other sources, the author presents a dynamic picture of each country's policy and development up to 2003.

This article reflects the author's personal opinion and is not an official statement of the European Commission.

#### **OVERVIEW: COMPARING THREE COUNTRIES**

Innovation is now a widely recognised goal of political efforts to stimulate the creation of knowledge and promote its application to develop new products that might foster economic growth and increase competitiveness. But an explicit innovation policy had not existed until 1980 when two innovation-promoting bills were approved in the USA, rapidly followed by similar measures in the leading European countries. A successful innovation policy is now believed to aim at the development of the national knowledge base, protection of new knowledge through patenting, transfer of knowledge from academia to industry to develop new products, commercialisation of these products, and stimulation of a favourable legal and social climate.

From the start, biotechnology was included in each innovation policy scheme as one of the priority fields. In Germany, the chemical industry federation DECHEMA published a strategy paper in 1974;<sup>1</sup> in France, Jean-Claude Pelissolo proposed the 'Mission for Biotechnology' in 1980;<sup>2</sup> and a British

working party, chaired by Alfred Spinks, presented an influential report in 1980.<sup>3</sup> All three documents stressed the need for an orchestrated, cooperative strategy to stimulate the development of biotechnology at national level. Governments pledged relatively modest funds in the beginning to stimulate basic research and development of technologies: Germany allocated DM70m [ECU35m] through the 'Leistungsplan 04' in 1980;<sup>4</sup> France spent ECU36m in 1982;<sup>5</sup> the UK funded £,28.8m [c. ECU 45m] through three research councils over 1981-82.6 Now, 20 years later, current government funding is as follows: Germany provided €703m from the research ministry, plus €357m allocated to the large research institutions (2003; not including the considerable Länder funds);<sup>7</sup> France spent FF16.6bn [€2.45bn] on life sciences (2002; of which FF250m was dedicated to biotechnology);8 the UK allocated £,259.1m [€415m] through the BBSRC alone (2003/04).9 These figures do not include regional funds, infrastructure costs, financing by charities (amounting for the UK alone to 17 per cent of total public spending on

340

biotechnology R&D), and salaries for civil servant researchers. The 20-fold, or (in the case of Germany) even 30-fold, increase is a strong indicator for the success of biotechnology, and life sciences in general, underlining the continuously high interest of all three governments in this field.

Of course, policies have changed over the past 20 years. Initially, policy-makers focused on stimulation to develop new technologies and promote modern biotechnology. Only later was the crucial importance of patenting discovered. Academic researchers were traditionally interested in publishing results, not in protecting inventions. There was little incentive for them to do so, not only in the UK where the British Technology Group took care of patent applications, but also in France and Germany where patents belonged to the institution, and German professors could protect their intellectual property only when the university was not interested in doing so. As a consequence, 79 per cent of all German biotechnology patents registered in 1994 came from industry, 12 per cent from research institutes, and only 8.7 per cent from individual researchers.<sup>10</sup> Even though today the legal situation has changed, patenting has not much improved, because educational institutions are crucially lacking patenting advice and support to researchers.

Still, success fell short of expectations, and the reason for failure was identified as insufficient transfer of the new technologies and knowledge to the economy. At European level, a common legal framework for biotechnology was decided in 1990, but slowly implemented into the legislation of some member states. European countries still counted low numbers of biotech companies (Germany 75, France 75, UK 140; all figures for 1995),<sup>11</sup> whereas the USA had reached the threshold of 1.000. Shortcomings were identified in providing capital, and in training scientists as biotech managers. Germany had literally no venture capital market for

biotechnology. The federal government decided to stimulate the creation of venture capital through seed funding<sup>12,13</sup> – the same measure was taken by France.<sup>14</sup> Furthermore, bio-incubators were set up to help young companies get started. By 2002, the success of these political stimulations showed in largely increased numbers of dedicated biotech firms: Germany 360, France 240 and UK 330.<sup>15</sup> The number of publicly traded companies, however, is revealing of the industrial robustness: Germany counted 13 in 2002, France six, but the UK 46.<sup>15</sup>

The efficiency of industrial R&D can be considerably increased through improved technology transfer and cooperation. All three governments came to the conclusion that this efficiency could best be achieved by creating clusters of private companies in close vicinity to high-level universities, such as Cambridge, Oxford and London in the UK; the 'biopôles' Paris, Lyon and Nice in France; or the 'Bio-Regionen' Heidelberg/ Mannheim, München, Berlin and Köln/ Düsseldorf in Germany (to mention only the most important examples). Also, the three governments identified genomics as a key field for future biotechnology development and promoted the concentration of know-how and equipment in some clusters: France has set up seven 'génopôles', providing €75m from 2002 onwards;<sup>16</sup> Germany created the National Genome Research Network, allocating €175m over 2002–2004;<sup>17</sup> and the UK has been funding a network of genetic research centres since 2002.<sup>18</sup>

Neglecting public acceptance is believed to have led to the current political difficulties in agrofood-related biotechnology. In fact, the rather optimistic public opinion of 1991 (when the first Eurobarometer survey was carried out) decreased in two countries: France slid from fourth place in approval of biotechnology to fifth in 2002; the UK fell from sixth place to 14th; whereas the pessimistic (West) Germans remained at the 15th place, just before Luxembourg. All three countries have a quite well-

#### Only later was the crucial importance of patenting discovered

The UK, French and German governments identified genomics as a key field for future biotechnology development EPOHITE results enabled the 14 countries to be grouped into four clusters according to their performance

The three countries accounted together for 80 per cent of public biotechnology R&D spending in Europe informed public, though, scoring sixth (UK), seventh (France) and eighth (Germany), respectively, on the knowledge scoreboard. The difference, however, shows in the readiness to get engaged in the public debate: the French being very engaged (fourth), and the British somewhat (seventh), while the Germans are lagging behind, just at the EU average.<sup>19,20</sup>

## NATIONAL ASSESSMENT: THE EPOHITE STUDY

The forementioned countries accounted together for 80 per cent of the public biotechnology R&D spending in Europe. How did they compare in their biotechnology policies? A team of researchers from various European countries tried to find an answer to this question by initiating the Commissionfunded EPOHITE project. The participants based their work on the results of an earlier project most of them had conducted, the so-called 'biotechnology inventory', a collection and analysis of all available data on the public biotechnology R&D policies in 14 member states, as well as Iceland, Norway and Switzerland, over the period 1994–98.<sup>21</sup> By analysing the roles of the various actors and the use of the political instruments, the EPOHITE team sought to assess the effectiveness of the national innovation policy of each of the 14 member states considered in relation to biotechnology, extending the scope by including recent data up to 2001. The team considered mainly the biotechnology-specific policies designed to strengthen the knowledge base, support commercialisation and favourably influence the public debate, but also analysed non-specific horizontal policies favouring the development and application of innovative technologies. Special attention was given to the harmonisation of relevant regulations to avoid disincentives for industry in countries with more stringent rules. Finally, the availability of financial capital in high-growth sectors had to be taken

into account as a crucial factor for industrial development.<sup>22</sup>

EPOHITE results allowed the 14 countries considered to be grouped, according to their performance, into the following four clusters:

- The first cluster was made of the bestperforming countries, Denmark, Sweden and Finland. These are countries with a long tradition of industry—academia collaboration, willing to allocate sufficient funding to biotechnology, recognising scientific excellence, and emphasising direct support to industry by supplying credits and loans.
- The second cluster integrates two large (UK, Germany) and two small countries (Belgium, the Netherlands) showing a rather strong heterogeneity. Except for the Netherlands, these countries have relatively larger budgets compared with the best-performing countries, but fewer sources for R&D across all fields. They have implemented instruments targeting the whole innovation process and, at least Germany and Belgium, give strong support to small and medium-sized enterprises (SMEs) in the biotechnology sector.
- The third cluster of intermediate performers (Austria, France and Ireland) is also remarkable by their very different framework conditions. Ireland has entered the competition as a rather successful latecomer, whereas France performs behind the other two traditional big players, Germany and the UK, showing that the organisation of public sector research and universities matters more than the mere value of research budgets. For all members of this cluster, technology transfer measures and commercialisation are priorities, Ireland in particular attracting multinationals.

• The fourth cluster, finally, put together the weak performers of Greece, Italy, Portugal and Spain. They suffer from small budgets for biotechnology, neglect of the broad range of policy instruments, lack of support for the commercialisation of scientific results from public research, and little attention to relevant regulations, including protection of intellectual property.

A thorough analysis of the EPOHITE findings leads to the following conclusions or recommendations:

- Political instruments for allocating funding are crucial, not large budgets.
- A competitive knowledge base has to be set up and renewed in order to be successful.
- Effective technology transfer instruments are critical.
- The different policy approaches must be well coordinated to target all aspects of the innovation system.

## FRANCE: RELATIVELY UNDERPERFORMING

France had to start the biotechnology era with serious handicaps, compared with her main competitors. The industrial pharmaco-chemical base was much weaker than in the UK and in Germany, countries with world-class chemical and pharmaceutical companies. The centralised structure of public research was unfavourable for quick adaptations; also researchers' lack of interest in potential applications and the institutional ownership of patenting inventions funded by public money led to decreasing numbers of patents registered whereas the number of scientific publications increased. The political starting signal initiated a whole range of smaller and larger programmes of limited effect. Besides the national programmes,

considerable funding to various biotechnology-relevant projects has been provided by the agencies involved in research, such as the *Centre National de la Recherche Scientifique* (CNRS), the *Commissariat à l'Energie Atomique* (CEA), the *Institut National pour la Recherche Agronomique* (INRA), and the *Institut National de la Santé et de la Recherche Médicale* (INSERM).

As a reaction to the perceived need to speed up commercialisation of products, the unique programme BioAvenir was adopted to run from 1992 to 1997, and allocating ECU230m of public funding, mostly to Rhône-Poulenc R&D.<sup>23</sup> However, its impact was judged insufficient, and the focus on one big company denounced as counterproductive.

In 1997, Claude Allègre, then Minister for Education, Research and Technology, announced a refocusing of innovation policy on SMEs as generators of knowledge and employment.<sup>7</sup> SMEs were at the core of the new concept of the biopôles, clusters of research-intensive companies and public research institutes, each cluster focusing on a different life science area. Genomics had been identified as the core competence for biotechnology competitiveness in the 1999 report of the French Academy of Sciences.<sup>24</sup> A specific National Genomic Programme (1999–2002, providing €67.5m in 2001) was followed by the Consortium National de Recherche en *Génomique*,<sup>6</sup> a foundation-like structure to coordinate the national core facilities and the network of génopôles that have been set up in seven regions by the end of 2003.<sup>25</sup> The typically French top-down approach attracted much criticism but was praised by an assessment study prepared in 2002 for the French government by the European Molecular Biology Organisation (EMBO). The rather enthusiastic report confirmed the effectiveness of the French scheme for swiftly creating knowledge and transferring it to applications, although the administrative burden was found

EPOHITE findings lead to four conclusions or recommendations The Innovation Act and the decision to set up 'bio-incubators' have resulted in the fostering of a range of start-ups

Mme Lenoir concluded that French efforts in life sciences are especially lacking

Despite large public R&D spending, France remains a problemladen, relatively weak player heavy, purchase of new equipment cumbersome, and skilled staff discouraged by short-term contracts.<sup>26</sup>

Following the publication of the Guillaume report, in 1998, the Innovation Act<sup>27</sup> and the decision to set up so-called 'bio-incubators' (1999)<sup>22</sup> have resulted in the fostering of a range of start-ups, while investment and skilled workforce have remained insufficient. From 1995 on, the biotechnology industry developed rapidly, not least due to the support of the Agence Nationale de la Valorisation de la Recherche (ANVAR), the technology transfer agency, which increased its subsidies from €5.5m in 1996 to €23m in 2002. In order to maintain growth, and to overcome the financing crisis in the biotechnology sector, France launched the Plan Biotech 2002, providing €60m seed venture fund to start-ups, and €90m in bank loan guarantees.<sup>28</sup> Naturally, France turned to the exploration of the country's natural resources, focusing on agro-food applications, which have now become a vulnerable orientation because of the critical public attitude. A stronger orientation towards diagnostics and therapeutics in both human and veterinary medicine could probably help to avoid a downturn.

Mme Noëlle Lenoir concluded in her assessment report, published in 2002,<sup>29</sup> that French efforts in funding research are generally weak (2.2 per cent of GNP), in life sciences especially insufficient (3.3 times less per capita than in the USA), the research workforce is ageing, the attraction of sciences has generally diminished, and post-docs prefer to go to the USA where working conditions are better. She found also strong points: scientific training has a high level; some laboratories are renowned worldwide; and the quality of the health system has been recognised by the World Health Organization.

The originally favourable public attitude to biotechnology deteriorated following the discovery of genetically modified (GM) maize being shipped from the USA to France in a rather silent, albeit not illegal, way. This event gave a strong push to biotechnology opponents and forced the government to a very prudent stand on GM food, apparently a sensitive topic in a country proud of its tradition of high-quality food.

#### **EPOHITE** assessment

The country was successful in creating new firms and support industrial growth, although the number of firms per capita remains low (about three per million, compared with over 18 for Sweden). France lost out in scientific publications (130 per million capita) and patents, especially in the fields of genomics where it is only now catching up. Patents are assigned to the research organisation, so there is little incentive for the researcher to become active. On the knowledge base, France has scored only 7.34 (ninth place), whereas she fared much better for per capita expenditure for biotechnology R&D: ECU35.9 per million over the period 1994-98 (fifth place). France has been rated weak in both vertical and horizontal policies, together with the southern countries. Public policy has been perceived as complex, redundant and rather inefficient, considering the multiple levels of intervention and the small amounts of money versus a large number of constraints. Scientific careers are not sufficiently attractive to ensure a sustainable growth of the knowledge base. Hence, despite the third-largest biotechnology R&D spending in Europe (ECU2,115m, 1994-98) and a strong public commitment, France remains a problem-laden, relatively weak player. The challenges ahead are to accelerate academic growth and consolidate the firms having the potential for sustainable growth.22

#### THE UK: STILL LEADING

Based on a strong chemical and pharmaceutical industry as well as an excellent science base, the UK started early into the biotechnology era. Biotechnology development ran fairly It was a major task for the British government to overcome the dichotomy between industry and academia in order to foster technology transfer

In 2002 the British government recognised the importance of a collaborative approach to genomics by funding a network of scientific research centres smoothly, owing to the liberal British economic tradition, compared with the more bureaucratic structures of her main competitors on the continent. Nevertheless, the drawback came from the business-disdaining tradition of academic researchers. Hence, it was a major task for the British government to overcome the dichotomy between industry and academia in order to foster technology transfer.

In this spirit, the research councils jointly launched the LINK programmes in 1988, designed to promote partnerships between industry and the research base through long-term, applied research projects. Since then, about 15 LINK programmes have been running to promote R&D in various life science fields. Other business-promoting schemes followed, such as the Teaching Company Scheme, Biotechnology Means Business (run by the Department of Trade and Industry [DTI]) and Bio-Wise. The latter, also set up by the DTI, is aiming at improving UK competitiveness and helps the biotechnology industry to take advantage of developing markets in the UK and overseas.<sup>30</sup> Enhancing industrial competitiveness was the main reason for launching the Biotechnology and **Biological Sciences Research Council** (BBSRC), in 1999. The BBSRC is also promoting research and training in biological systems. More recently, the government recognised the production bottleneck as an obstacle to future biotech industry growth, and addressed it by the 'Manufacturing for Biotechnology' initiative (1999), aimed at helping SMEs to enhance their manufacturing potential.<sup>30</sup> The cooperation of companies engaged in the new biotechnology areas was addressed to by the creation of the so-called 'clubs': technology platforms focusing on specific topics.

A special feature is the 'clustering' of biotech firms and research institutes in places selected for scientific excellence (such as Cambridge with 170 companies, London and Oxford). Once a cluster has

reached a critical mass of firms and people, knowledge exchange happens easily, networks form, infrastructure adapts, business support services expand, and technological convergences lead to new innovations. This scheme is based on the same principles as the French biopôles and the German Bio-Regionen, although in the UK it is not believed that every region should have such a cluster.<sup>31</sup> Clusters and incubators have been supported with  $\neq$ ,50m annually from regional innovation funds since 2001.<sup>32</sup> The success of the bio-incubators may be illustrated by the increase of spin-off companies: 70 in 2000; 203 in 2001; and 248 in 2002.<sup>33</sup> In 2002, the British government recognised the importance of a collaborative approach to genomics by funding a network of genetic research centres. Six Genetics Knowledge Parks will be based in different regions, enhancing the potential of the already existing clusters.<sup>18</sup> The maintenance of the knowledge base has not been neglected over technology transfer and commercialisation issues: one of the three 'cross-council' programmes established in 2001 covers post-genomics, including the promising proteomics area (funded with  $f_{246m}$  from 2001 to 2006), and a recently approved programme on stem cell research ( $\pounds$ ,40m from 2003 to 2006).34

The results of the early start and adequate policy measures are obvious. Today, the UK has the largest and most profitable biotech companies in Europe (about 400 in 2003, employing over 18,700 people); the largest number of public companies (43); the strongest financial market (London Stock Exchange); the best research environment (180 biotechnology publications per million capita in 2000, ie the sixth best in Europe, but still ahead of France and Germany); the second-highest R&D funding (ECU2,572m over 1994–98,<sup>21</sup>); it accounts for 49 per cent of products in the pipeline of European public companies and for 62 per cent of new products in late-stage development;<sup>35</sup>

and, indeed, the most products on the market.  $^{36}$ 

Nevertheless, a few problems remain: the lack of interest among young people to make a career in the life sciences; the relatively high rate of brain drain to North America (although debated); the vulnerability towards the global financial market (the UK sector raised  $\neq$ ,1.84bn over 1999-2000, albeit much less since then<sup>15</sup>); and the shortfalls expected during the consolidation phase which has now started, several years behind the USA, but ahead of the rest of Europe. There are still some problems in attracting sufficient investments to biotech firms. The Biotechnology Industry Association (BIA) was proposing measures similar to those applied in Germany to obtain government money in the form of low-interest unsecured loans which could double or triple the effective amount of the venture investment.37

An additional problem surfaced with the introduction of GM food products on the market. In spite of a promising start, in the wake of the BSE scandal, the British public turned around and massively opposed GM crops, although real opposition may be difficult to distinguish from the high-profile campaigning efforts of some nongovernmental organisations (NGOs). Additionally, the traditionally strong animal rights activists are hampering industrial research. The number of crop scientists employed by industry declined by more than 60 per cent over the last 20 years, most of them since 1999, and four big companies have closed their crop research facilities in Britain in the past three years.<sup>38</sup> A recent report by the Bioscience Innovation and Growth Team<sup>39</sup> shared these worries about the siphoning effect of the USA and recommended political measures.

#### **EPOHITE** assessment

The UK remains the leading country in the biotech and pharma sectors and is highly successful in encouraging collaborations between universities and

industry as well as in commercialisation, seeing a steady increase in commercial activities over the period 1995-2000. Project funding has some pitfalls because of the agency-based funding structure, making coordination difficult. Recruitment is sometimes difficult because of low pay, lack of career structure and negative public image of science. Although collaboration schemes are widely used, small firms have to invest an unreasonable amount of work and time to receive ultimately too little money. A major problem turned out to be the differences in the patent and legal systems between the EU and the USA, the latter market being of special importance to British firms. Furthermore, the public hostility towards some aspects of biotechnology (animal use, GM crops and foods) is a disincentive to certain research and production activities. The dependence on stock markets is crucial: the changing of the guidelines of the London Stock Exchange for a public flotation was more important for industry than the government promotion over the same time.<sup>22</sup>

## GERMANY: COMING FROM BEHIND

Although traditionally strong in basic and applied research, and having a world-class chemistry and pharmaceutical industry, Germany started with difficulties into the biotechnology era. The big companies had limited interest in promising but as yet unproven technologies. The few smaller companies set up early all vanished for lack of public support and capital sources. The federal government launched a long series of biotechnology programmes, which adapted gradually to the emerging needs of the biotechnology stakeholders, although remaining focused on research. Hence, biotechnology R&D developed in Germany mainly in large companies, public research centres and university laboratories; by 1995, no more than 75 firms were active in the field,<sup>11</sup> Academic researchers, deeply rooted in the traditional separation of academia and

A major problem turned out to be the differences in the patent and legal systems between the EU and the USA

An additional problem surfaced with the introduction of GM food products on the market In the early 1980s, Germany held 20 per cent of biotechnology patents worldwide ... in the mid-1990s she held only 12 per cent

Regional investment is very strong. Understandably, Germany has chosen an action plan on a regional level: the BioRegio scheme

The core problem has remained a lack of investment business cultures, were risk-shunning and, anyway, not interested in applying their discoveries to product development which led, as in the UK, to the paradoxical situation that potentially important discoveries were more easily developed abroad than in the country of origin.<sup>40</sup> The concept of start-ups and spin-offs was completely unknown in Germany. Although the first venture capital fund had been created in 1975, it ignored the biotechnology perspective.<sup>41</sup> In the early 1980s, Germany held 20 per cent of biotechnology patents worldwide, being second only to the USA; however, this lead eroded, owing to political and financial problems, to a mere 12 per cent in the mid-1990s.42 (In 1999/2000, Germany held 33 per cent of all EU biotechnology patents.<sup>22</sup>)

The key role in biotechnology R&D management was played by the Bundesministerium für Forschung und Technologie (Federal Ministry for Research and Technology [BMFT]) and, more recently, its successor, the Bundesministerium für Bildung und Forschung (Education Ministry [BMBF]), which became the focal point for concentrating all federal efforts to promote biotechnology R&D, a rather efficient approach compared with the dispersed responsibilities of the French and British agencies. The most recent programmes were, or still are: Biofuture (funding young scientists); Biochance (supporting pre-competitive research); BioProfile (asking regions to shape unique local profiles of competences in one specific area); Biotechnologie 2000 (funding a broad range of projects); GABI (plant genome research);<sup>43</sup> and the National Genome Network (see below). During 1994-98, Germany spent a total of ECU3,021m for public biotechnology R&D, then the highest sum in Europe.<sup>22</sup>

Germany identified genomics as a key field to many biotechnology areas, and decided to support it through special measures. Announced in 2001, the National Genome Research Network involves 16 universities, several MaxPlanck Institutes, and four national research centres, and has received \$175m (€145m) during 2002–04.<sup>16</sup> However, this money came from the selling of a public telecommunications company, and the government, bound to budget cuts, might be in difficulties to maintain the network in the present form.

The regional investment is very strong, owing to Germany's federal tradition, the Länder supporting the universities and contributing substantially to the budgets of the large research centres (such as Max-Planck Institute, Leibniz-Gesellschaft, Fraunhofer Institute). It is understandable, then, that Germany has chosen an action plan on regional level, the BioRegio scheme, which created favourable conditions for competition between various cooperation projects, bringing together administration, industry and finance actors. As a result, biotechnology transfer has been spurred in 17 regions (not corresponding to the Länder), leading to the largest total number of start-ups and companies in Europe, rekindled research efforts, and creating a considerable number of new products in the pipeline. The real value of the action plan was seen not so much in augmenting the number companies but in enhancing awareness beyond the biotechnology sector.44

On the other side, one core problem has remained: a lack of investment, despite considerable efforts in the past. The Technologie-Beteiligungsgesellschaft (tbg) had provided a total of €372.8m,<sup>45</sup> from 1994 to 2002, as seed capital to 170 companies on the only criterion of having received venture capital from another source. Now, with tbg applying stricter rules to applicants, and venture funds drying out, the prognosis is rather bleak for many of the too small and underfinanced firms, while the alternative financing tool Neuer Markt, opened in 1997, where most of German public companies were listed, had to be closed down in 2003.

In October 2003, the Economics and Labour Ministry (BMWA), recognising

Between 1997 and 2003, German companies obtained approvals for six products from the EMEA, representing 30 per cent of all approved biotechnology drugs in the EU

The results present a mismatch between the evolution of the knowledge base and commercialisation activities

the need to foster SMEs, announced the set-up of a €500m fund that will invest in venture capital funds, while the BMBF will use €100m in tax money for its BioChancePLUS programme to cofinance R&D projects in SMEs.<sup>12,13</sup> Nevertheless, Germany has now about 360 biotechnology companies, of which only 20 have gone public yet, employing 13,400 people (7 per cent less than in 2001), and showing a combined turnover of about €1bn.<sup>46</sup> Between 1997 and 2001, German companies were successful in obtaining approvals for six products from the European Agency for the Evaluation of Medicinal Products (EMEA), representing 30 per cent of all approved biotechnology drugs in the EU.<sup>22</sup>

Safety regulations, patterned on the US ones, were proposed in 1979 but skipped by the BMFT in favour of self-control, carried out by experts and representatives of industry and labour: the typical approach of a corporatist state.<sup>42</sup> In the late 1980s, under the impact of protests from oppositional groups outside parliament, the government was forced to establish a framework of impractical genetic engineering laws which came under fire from the biotechnology industry, pressing for a profound review of the criticised rules. Even the revised 'Gentechnikgesetz' (1992) proved to be the most stringent one in Europe (beside the Danish law perhaps), considerably hampering the development of products. In 1993, therefore, the USA had 130 biotechnology-based therapeutics in the pipeline, and Japan 80; Germany had only four products in clinical trials.<sup>47</sup> The difficult implementation of the recent EC directives shows that the political climate has not changed at all in Germany. Public opinion in Germany has been highly influenced by oppositional groups, biased media coverage and fears of 'genetic manipulation' stemming from the eugenics activities under the fascist regime.

Germany has yet to realise that the biotechnology industry is neither the miracle remedy to reduce unemployment massively and boost the sluggish economy, nor the looming catastrophe as painted by the strong oppositional groups now represented in the government. Furthermore, the country has to face a considerable lack of skilled personnel and the pull from the huge biotechnology potential of the USA; and it is still far away from the consolidation phase which will prove fatal to most of the undercapitalised start-ups. Nevertheless, it has made considerable progress over the last ten years and will enter the maturing phase with a strong science base and increased confidence.

#### **EPOHITE** assessment

Germany's biotechnology sector profited from the mechanisms supporting the healthcare sector, the gradual increase of the share of public funds destined to biotechnology, and the network formation between actors interested in biotechnology development. The focus on technology transfer instruments and the availability of financial capital have yielded the expected results. Although public perception is in general supportive, conditions for the industry appear to be overregulated. Germany presented only an average performance in improving the knowledge base (seventh place), having a publication growth rate of 50 per cent (below the European average of 58 per cent), but a citation rate above the EU average. The results present a mismatch between the evolution of the knowledge base and the commercialisation activities, Germany being the strongest industrial player in terms of number of firms and venture capital raised (until 2001, at least). Therefore, despite the proven effectiveness of the political instruments implanted to stimulate the network formation and the commercialisation of scientific results, the moderate performance of the system in the creation of knowledge and the strong dependence of some industry actors on venture capital investment bring into question the longterm sustainability of the industrial activities.22

### CONCLUSIONS: THREE ACHIEVEMENTS

Although based on different preconditions and research infrastructures, the three countries have chosen to develop their biotechnology potentials and have reached similar results. Nevertheless, the EPOHITE study, as well as the comparative analysis over 20 years, ascertains considerable differences in degree of performance. Neither the disparities in the number of companies, nor the differences in providing capital really matter; even the different political approaches deeply rooted in traditional ways of governing are not decisive. The most important outcome of the various studies is the fact that biotechnology is now taken seriously by industry, finance and government willing to cooperate in the best possible way to develop this important sector further to maturity and making it fully competitive in a world where competitors other than the USA will soon have to be reckoned with. Hence, there is no loser and no winner in the fairly small European biotechnology race, just strong performers with different handicaps to be overcome - not at least by international cooperation on the European level. The following summary, therefore, is not a scoreboard but an indicative list of strengths and weaknesses.

France shows weaknesses in maintaining the knowledge base, especially the patenting of academic inventions is insufficient. Although public R&D spending for biotechnology is high, administrative problems and lack of coordination between the agencies are reducing the effectiveness of investments. Nevertheless, France did manage to create a considerable number of SMEs and technology clusters with incubator facilities.

The UK, having started from an already high level of innovation, still remains number one in terms of quality of the knowledge base, patenting activities, technology transfer and business management. However, the rather ineffective public spending policy, limitations in attracting private capital, and lack of skilled personnel are slowing down the industrial development.

Germany, for so long based on her strong chemical and pharmaceutical industries with little interest in biotechnology, had to catch up by promoting the knowledge base, enabling academic researchers to seek for patent protection, and stimulating technology transfer by ingenious schemes to get valuable results. Most of the German biotechnology industry, despite its quantitative success, is still comparatively weak and underfinanced and its development threatened by the traditional tendency to implement laws in a stringent way. The German public became aware rather early of the potential risks of biotechnology and contributed to the slow-down in the sector's development during the 1980s, whereas the French and British public perception shifted much later from technology-friendliness to biotechnology-scepticism, currently blocking commercialisation of GM crops and foods. This movement is reinforced in the UK by strong animal rights groups' activities hindering some biomedical research projects.

Therefore, one can consider France to be an underachiever, not realising her full potential and continuously catching up; the UK the leader who is slowing down in performance somewhat; and Germany a competitor with strong capacities, coming from behind and aiming for first place in Europe.

#### Acknowledgment

This article is a shortened version of an article 'Innovation policy in three European countries: The case of biotechnology', to be published in *Education et Formation*.

#### References

 DECHEMA (1976), 'Biotechnologie: eine Studie über Forschung und Entwicklung – Möglichkeiten, Aufgaben und Schwerpunkte der Förderung', written on behalf of the Ministry of Research and Technology, 3rd edn, Deutsche Ges. f. Chem. Apparatewesen, Frankfurt/M.

There is no loser and no winner in the small European biotechnology race

- Pelissolo, J.-C. (1980), 'La biotechnologie, demain?', Report to the Prime Minister, Secretariat of State for Research, Paris.
- Spinks, A. (1980), 'Biotechnology', Report of a joint working party, HMSO, London.
- Wess, L. (2002), 'Germany to increase biotech funding', *Biocentury*, 24th June, p. A14.
- European Commission (1983), 'Biotechnology: The Community's role', Background note on national initiatives for the support of biotechnology, EC, Brussels [COM(83) 328].
- Yoxen, E. J. (1984), 'Assessing progress with biotechnology', in Gibbons, M. *et al.*, 'Science and technology policy in the 1980s and beyond', Longman, London.
- Mcleod, Z. (1997), 'French government drops BioAvenir to kick-start small biotech', *Scrip*, No. 2289, p. 3.
- Pezet, A. (2001), 'Budget 2002: Priorité aux sciences de la vie', *Biotech. Info.*, No. 107, pp. 1–2.
- 9. URL: http://www.bbsrc.ac.uk/about/stats/ Welcome.html
- Friedl, C. (1995), 'Biotechnologie sucht Patentlösung', VDI Nachrichten, 29th September.
- Ernst & Young (1995), 'Biotech 95: Second Annual Ernst & Young Report on the European Biotechnology Industry', Ernst & Young, London.
- 12. Wess, L. (2003), 'More tax money for biotech', *Biocentury*, 27th October, p. A13.
- Sheridan, C. (2003), 'Germany biotech gets second chance', *Nature Biotechnol.*, Vol. 21, pp. 1414–1415.
- 14. Anon. (1998), 'French launch research initiative', *Scrip*, No. 2336, p. 3.
- Ernst & Young (2003), 'The European Biotechnology Report 2003: Endurance', Ernst & Young, London.
- Haiech, J. (2003), 'The French genomic programme and the National Network of Genopoles', Consortium National de Recherche en Génomique, Paris.
- Koenig, R. (2001), 'A big boost for postgenome research', *Science*, Vol. 292, pp. 29–30.
- 18. Anon. (2002), 'UK funds genetic research parks', *Scrip*, No. 2715, p. 3.
- INRA (Europe) (1991), 'Opinions of Europeans on Biotechnology in 1991', Report undertaken on behalf of the DG Science, Research and Development of the Commission of the EC, CUBE, Brussels.
- Gaskell, G., Allum, N. and Stares, S. (2003), 'Europeans and Biotechnology in 2002', Eurobarometer 58.0, Report to the EC DG

for Research, 2nd edn, European Commission, Brussels.

- Enzing, C. M., Senker, J. M., Reiss, T. *et al.* (1999–2000), 'Inventory of Public Biotechnology R&D Programmes in Europe', Vols 1–3, European Communities, Luxembourg (EUR 18886).
- Reiss, T., Mangematin, V., Enzing, C. M. et al. (2003), 'Efficiency of Innovation Policies in High Technology Sectors in Europe (EPOHITE)', Vols 1–2, European Communities, Luxembourg (EUR 20922).
- 23. Monsan, P. (2000), 'Twenty years of biotech in France', *Biofutur*, special issue, pp. 27–31.
- 24. McCabe, H. (1999), 'France losing genome race, says report', *Nature*, Vol. 400, p. 199.
- 25. Haiëch, J. (2003), 'Le programme Génomique: Interface entre les secteurs académique et privé', *Biofutur*, No. 232, pp. 50–53.
- 26. EMBO (2003) Review of the French *Genopôle* System', European Molecular Biotechnology Organisation, Heidelberg.
- Chopplet, M. (2001), 'Biotechnology and the bio-industry in France at the dawn of a new millennium', in 'BioCommerce Data's Biotechnology Company Compendium 2001/ 2: Europe', BioCommerce Data, Slough.
- Hodgson, J. (2001), 'French loan arranger seeks biotech posse' *Nature Biotechnol.*, Vol. 19, p. 1089.
- 29. Lenoir, N. (2002), 'Relever le défi des biotechnologies', Report to Minister Laurent Fabius, Paris.
- Sime, J. (1999), 'Sustaining the growth of UK biotechnology', *Nature Biotechnol.*, Vol. 17, pp. 442–443.
- Sainsbury of Turville, Lord (1999), 'Biotechnology clusters', Minister for Science, London.
- 32. Anon. (2000), 'UK proposals on innovation fail industry?', *Scrip*, No. 2567, p. 5.
- Sainsbury of Turville, Lord (2003), 'Royaume-Uni: Maturité et ouverture', *Biofutur*, No. 236, pp. 21–24.
- Anon. (2002), 'UK Puts Cash into Stem Cells, Energy, and Rural Issues', Research Europe, 19th December, p. 6.
- 35. Anon. (2003), 'New UK group to boost biotech', *Scrip*, No. 2836, p. 5.
- Sainsbury of Turville, Lord (2003), 'Comment: The UK Government's strategic approach to the biotechnology industry, *J. Commercial Biotechnol.*, Vol. 9(3), pp. 189–191.
- Hodgson, J. (2001), 'UK keen to mimic German venture scheme', *Nature Biotechnol.*, Vol. 19, p. 495.
- 38. Sample, I. and Meikle, J. (2003), 'Brain drain

threatens GM crop research', *The Guardian*, 25th September.

- 39. Anon. (2003), 'Will UK biotech survive? The BIGT report', *Scrip*, No. 2904, p. 6.
- Morris, R. W. and Schlüter, U. (1989), 'The Transfer of Biotechnology in the Federal Republic of Germany', Bundesmin. f. Forschung u. Technologie, Bonn.
- Jasanoff, S. (1985), 'Technological innovation in a corporatist state: The case of biotechnology in the Federal Republic of Germany', *Research Policy*, Vol. 14, pp. 23–38.
- Edgington, S. M. (1995), 'Germany: A dominant force by the year 2000?', *Bio/technology*, Vol. 13, pp. 752–756.

- Freitag, J. (2002), 'GABI the German plant genome research program', *The Parliament*, 30th September, p. 42.
- 44. Schropp, C. G. and Conrad, J. (2001),
  'Biotechnology in Germany five years after BioRegio', *Gen. Eng. News*, Vol. 21(16), pp. 6, 31, 66, 70.
- 45. Wess, L. (2002), 'Germany's shakeout', *Biocentury*, 21st October, pp. A1–A6.
- Wierzbicki, J. (2003), 'La traversée du désert des entreprises allemandes', *Biofutur*, No. 236, pp. 18–20.
- Kircher, M. (1993), 'Zur Situation allgemeiner und angewandter Gentechnik in Deutschland', *BioEngineering*, Vol. 9(2), pp. 15–17.