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Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development **03-Oct-2008**

English - Or. English

DIRECTORATE FOR SCIENCE, TECHNOLOGY AND INDUSTRY
COMMITTEE FOR SCIENTIFIC AND TECHNOLOGICAL POLICY

DSTI/EAS/STP/NESTI(2008)11
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Working Party of National Experts on Science and Technology Indicators

EXPERIENCES GAINED IN SURVEYING BIOTECHNOLOGY COMPANIES IN GERMANY

15-16 May 2008
OECD Headquarters, 2 rue André-Pascal, 75016 Paris

This paper provided delegates with an overview of the German biotechnology statistics data collection, under item 6f – Other recent country experiences - of the draft agenda.

Please note that the complete version of this document is only available in .pdf format.

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JT03251887

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Introduction

1. Modern biotechnology is gaining in significance in all areas of industry, as well as in everyday life. Biotechnological materials and methods are finding application - directly or indirectly - in a variety of products and processes. Biotechnology is not a self-contained, single industry but a field of technology in which applications are developed for a wide range of industry sectors. In order to document the utilisation of biotechnological developments, it is also necessary to identify the diffusion of these uses in the user industries. These include the pharmaceutical, chemical, agricultural, food and textile industries, among others.

2. In 2005, the Federal Ministry of Education and Research (BMBF) commissioned the consulting and communications company BIOCOM to construct and maintain the information platform *biotechnologie.de* with the goal of obtaining up-to-date and reliable data on the activities of modern biotechnology. An essential element of this assignment was to conduct an annual survey of biotechnology companies in Germany.

Methodology of the survey

Definitions

3. Definitions of biotechnology segments, categories and techniques were used in keeping with the guidelines laid out by the OECD in the Framework for Biotechnology Statistics.

Implementation of the survey

4. As a result of the manageable size of the identifiable core population on the one side, and the high variance within the totality of the companies on the other, only highly comprehensive surveys can be regarded as suited for the compilation of statistically sound and comparable statements on the biotechnology sector. A questionnaire was developed for this survey that is based both on the OECD definitions as laid out above, and on the OECD's own 'model questionnaire'. Here, the aim was to combine a high level of information width and depth with manageable size, as well as a high degree of intelligibility.

5. To achieve this, a number of changes were made to the original draft (compare with the copy of the questionnaire in the Appendix):

- For questions concerning applied techniques, no distinction was made between the implementation of research and/or development services and applications for production purposes, as these activities are usually not clearly distinguishable.

- The question relating to activity in the various segments within biotechnology has been extended to include quantitative data, as these are essential for determining the maturity and economic performance of the companies. Furthermore, in order to undertake an analysis of the applied business models, a distinction was made between services and product/process development.

- In the financial figures, the amount of public funding received was included as an additional entry.

- The question in the "model questionnaire" on the number of biotechnology-related patents and patent applications was not included, as these can already be well researched through publicly accessible databases.

- Likewise, a further question from the original questionnaire on possible obstructions for companies was also not included, as this did not conform to the conventional quantitative data being surveyed.

- The participating companies were given an opportunity to create a short profile solely for the purposes of publication on the biotechnologie.de website.

- In the 2008 survey, for the first time a question was included on production capacity – both for biopharmaceuticals as well as for small molecules.

- In order to minimise hurdles for the completion of the survey, the essential data for each company, as well as the company profile (in each case taken from the previous year's survey) were pre-printed on the questionnaire. Companies therefore only needed to enter information in order to make corrections.

- The questionnaire was designed so that it could be printed on a double-sided A3 sheet. This manageable scale supports the willingness of recipients to participate in the survey.

6. The questionnaire was dispatched in the first quarter of every calendar year to all companies listed in the BIOCOM database as 'biotechnologically active' in Germany - a figure that currently stands at around 600. Over the course of every year, the database entries are continuously supplemented and revised. Used hereby are a number of publicly available sources. In line with OECD guidelines, in the selection of companies care was taken to include all companies in Germany that deal with biotechnology and that are based in this country. Thus, companies that are majority-owned by a non-German parent company, but which have a permanent premises in Germany were also taken into account. In the collection of job figures, business figures and business fields, only the German sites of a company were applicable in the survey. If a company has more than one location in Germany, it is only taken into account a single time, and with appropriate cumulative values. The deadline for submissions was the 31st of December of the previous year.

7. The companies were given a six-week deadline for the return of the completed forms, by fax or mail. After this period, those companies that had not replied received a follow-up via email and fax, which was possibly followed by direct telephone contact. All received information was reviewed for plausibility by competent persons, and was compared with other information sources. This multilevel procedure, developed by BIOCOM and undergoing continual improvement, has been successfully applied for around 15 years, and regularly gives return rates of around 90%. The period between the commencement of the survey and the production of a final report is, at a maximum of four months, relatively short, and at the same time, the resulting data is of high reliability and consistency.

Key figures in the biotechnology sector 2007

The structure of the biotechnology sector

8. In 2007, a total of 496 companies in Germany dealt exclusively or predominantly with modern biotechnological procedures and are thus defined by the OECD as dedicated biotechnology companies. Here, the figures remain largely unchanged from the previous year (495). For a further 91 companies, biotechnology is a business activity alongside others. Included in this group in particular are pharma firms as well as chemicals and seeds manufacturers. As a result of deeper data collection methods, the total number has increased significantly from 56 in 2006 to 91 in 2007. 46% of these companies are active in the health sector, 36% in agriculture and 12% in industry. Unless otherwise indicated, the following information from the survey refers exclusively to the dedicated biotech enterprises.

9. Regarding the founding dynamics, 2007 showed only a slight decline. 14 new companies were founded and 13 ceased operations – either as a result of acquisition or insolvency. On average, the biotech companies are eight years old. Approximately 30% have been active for ten years or more, whereas 16% were only founded in the previous three years. To date, the largest founding wave in German biotechnology was following the BMBF's 1996 BioRegio competition, which was active from 1997 to 2001. More than 40% of all biotech companies operating today began their business activities around this time.

Employee structure

10. Although the number of companies remains largely unchanged from the previous year, the total number of employees showed a slight increase in 2007. Thus, the 496 dedicated biotech companies had 14,360 employees on their books, a growth of 1.5% on the previous year. Just over 45% of these employees have a university degree. Furthermore, 15,210 of the total figure are employed in the biotechnology-related business areas of pharmaceutical, chemical or agricultural companies, a slight increase again of 2.8% on 2006. With this, the total number employed in commercial biotechnology in Germany is 29,570, 2.1% more than the previous year, and slowly approaching the 30,000 mark.

11. As regards company size, a majority of 86% is still very small. 43% of biotech firms employ less than 10 people, and a further 43% employ up to 50 people. This distribution is largely unchanged from the previous year. On the other hand, the number of companies that employ over 100 people has risen almost one third from 20 to 26, indicating that there is a small group of growing and prospering companies with increasing maturity. In contrast, the number of companies with more than 50 employees is unchanged, remaining at about 64 (2006:65).

Fields of activity

12. The main activities of the biotechnology companies are little changed compared to the previous year. 216 companies (44%) develop new medicines or diagnostic tests for the field of human or animal medicine. Thus, health or "red" biotechnology remains the most important industry segment.

13. An almost equal number of firms undertake activities that are not focused on one particular sector. Thus, 196 companies (40%) are defined by the OECD as being involved in non-specific applications of biotechnology. Included in this category are companies that exclusively or predominantly provide services for the biotechnology industry or are suppliers for biotech firms. Companies that carry out contract-based production of biological molecules without conducting any development themselves are also included in this category. This is the second most important segment of the sector, and will likely soon be as significant as medical biotechnology.

14. Much further behind, accounting for 38 firms (8%) in Germany, is industrial or 'white' biotechnology. Here, the core fields of activity are the development of technical enzymes, new biomaterials, or biotechnological production processes. Nevertheless, it should be taken into account that although this field of activity is not a focus of dedicated biotech companies, it is very important for the chemical industry. For this reason, the economic relevance is likely much greater than the data would suggest.

15. Only 26 companies (5%) belong to the category of 'green' or agricultural biotechnology. Much like industrial biotechnology, this field is dominated by large companies, suggesting that the economic relevance is also much greater than the data might indicate. A further 14 companies (4%) are active in the field of bioinformatics, which is gaining in importance for an ever greater number of applications.

16. Most companies (88%) undertake their own research activities; 52% are also active in product development, and more than a third (35%) of the companies are manufacturing actively. The fact that two thirds (68%) of the companies have declared that they provide services shows that the so-called dual business model – own product development, plus creation of turnover through the provision of services – has become firmly established in the biotech sector. The increasing maturity of the companies can also be seen in the progress made in product development. At present, drug candidates from 81 of the dedicated biotechnology companies in Germany are in clinical development. In 2007, these enterprises had a total of 127 candidates in clinical studies of phase I, II and III. The majority (104) is still in early development (I+II). The more advanced pipeline of the companies is comprised of 28 candidates, including five in approval process and 23 in phase III studies. Compared to the previous year, the number of advanced candidates has doubled.

Development of turnover and R&D expenditure

17. In 2007, the dedicated biotechnology companies created a turnover of approximately two billion euros, a first for this sector. This corresponds again to an increase of 14%, as in the previous year. The figure includes proceeds from the sale of products and services, as well as up-front and milestone payments from license agreements. A total of four therapeutic products from German biotech companies were on the market in 2007. However, the majority of the turnover stems from services and the sale of biomolecular tools. In 2007, expenditure on research and development also climbed. In total, biotechnology firms invested about one billion euros in their R&D activities, 8% more than in the previous year. This increase is due in particular to the greater number of clinical studies undertaken by drug developers that are reaching more advanced phases. This, again, is a sign of the growing maturity of the sector.

Financing

18. Alongside conventional turnover, venture capital is a substantial source of financing for biotech companies in Germany. At present, a third of dedicated companies is at least partly financed by VC investors. 17 financing rounds totalling approximately 294 million euros were completed in 2007. Compared to 2006, this is a clear increase of 14% in invested funds. Dominated by large financing rounds, there were six rounds with a volume of more than 25 million euros. Raising money from public capital markets was more difficult in 2007. In total, listed companies saw capital increases of around 137 million euros, only half of the volume from the previous year. At that time, companies raised 227 million euros, not including Qiagen's 210 million-euro convertible bond. Only one company ventured a listing at the stock exchange in 2007. According to the information submitted to the survey, a total of 213 companies received public grants in 2006. These subsidies amounted to approximately 52 million euros, which is 10% of the total external financing of German biotech companies.

Conclusions

The significance and utilisation of statistical data

19. Biotechnological processes and products are playing an ever larger role in the modern economy. Biotechnology has the potential to solve many of the challenges of our time, such as achieving improved energy efficiency in industrial processes, providing resource-conserving procedures, or treating diseases that are currently non-treatable. Biotechnology - a typical cross-section technology - affects a wide range of different industries. There is not just a single biotech product, but rather a great many applications that utilise biotechnological processes and (intermediate) products, each in a different context. In order to analyse the diffusion of biotechnology in the various industrial sectors, and to utilise the inherent potential of this field of technology, it is of crucial importance to have access to reliable and internationally consistent data.

20. The value of the data for responsible persons in politics and administration is in:

- the identification of the position and function of biotechnology companies in macroeconomic value creation chains
- the analysis of the long-term development of biotechnology relative to other areas of technology
- the evaluation of the success of different technology-specific and broader funding measures
- the identification and, where appropriate, elimination of any obstacles for the field of technology in the scope of the framework conditions

Experiences gained through previous surveys of data on biotechnology

21. The methodology described in Part 2 has proven itself to be highly viable and successful. In particular, the reduction of potential hurdles for the completion of the survey through short, clearly structured questionnaires with pre-prepared basic information results in a high acceptance rate among recipients. Through consistent follow-ups via an assortment of channels, a remarkably high response rate of around 90% is achieved.

22. Another important point is the validation of the received data by employees experienced in the field, on the basis of proven information from other sources. This means that incorrect information can be detected and corrected, and that omitted data can be added. Also of central importance is the transferring of the information into a relational database system, which enables a largely automated analysis of the data to be carried out.

23. The applied definition of terms and the intelligibility of individual questions must be regularly evaluated and modified if necessary. In particular, the differentiation between business models with a concurrent quantification of product developments and their allocation to various segments within biotechnology in a two-dimensional response matrix is extremely complex and therefore vulnerable to false data. It should be noted that, in striving for the greatest possible exactness, in some respects a certain "grey area" remains in which it is often not possible to assign clear definitions. This largely concerns the differentiation between product developers on the one side, and service providers and suppliers on the other, as well as the decision as to whether the latter belongs in a specific segment of biotechnology or should be referred to as "non-specific". Also, the demarcation between dedicated biotechnology companies and innovative biotechnology-active companies cannot always be made clearly.

Possible future changes to the survey

24. The following measures are planned with respect to future surveys on the biotech sector:

- A review and, if appropriate, amendment of applied definitions of terms, after consultation with and under the coordination of the OECD.
- An optimisation of the survey through changes to the formulation and content of the questions.
- The inclusion of further relevant aspects (possibly replacing others), for example relating to technology transfer.
- The allocation of individual companies to specific functions within the value creation chains.
- A further analysis of the data in the context of other fields of technology and industry segments for improved identification of the position of biotechnology within the macroeconomic environment.

8. COMPANY PROFILE (FOR PUBLICATION IN THE BIOTECHNOLOGIE.DE DATABASE)

Please update and complete the following information for the BIOCOM database (BioTechnology Year and Address Book).
If you must make substantial amendments to previously submitted information, please use a separate sheet or send an e-mail to **s.ding@biotechnologie.de**.

Our company collaborated with (list partners [firms, institutes, associations] involved in your company's existing co-operations):

Production (provide a short overview of your company's range of products; trade names may be used, but please avoid advertising statements):

Research (provide a comprehensive description of your company's research activities):

Services / Other (provide a comprehensive description of the range of services offered by your company):

Distribution (list the products and services that are distributed by your company):

We agree to the publication (free of charge) of our answers to the questions in Sections 1 (Basic Data) and 8 (Company Profile) online at the internet portal www.biotechnologie.de, as well as in the print edition of the BioTechnology Year and Address Book 2008 (BIOCOM).

_____ _____

Place / Date Signature

Company Survey Biotechnology in Germany 2008

Survey performed by the internet platform www.biotechnologie.de
By order of the German Federal Ministry of Education and Research (BMBF)

The following company survey is conducted according to current guidelines laid out by the OECD for the Biotechnology Statistics Framework.
The latest version of the OECD Guidelines, as well as the underlying definitions, are available at www.biotechnologie.de (under the heading "Facts and Figures").
Please send the completed questionnaire in the **enclosed envelope by March 25th, 2008** to biotechnologie.de (c/o BIOCOM, Stralsunder Str. 58-59, 13355 Berlin). If you have any questions, please don't hesitate to contact the biotechnologie.de team at **+49 (30) 264921-47**.

1. BASIC DATA

Company:			
Street/Post box:			
Postal code/City:			
Phone:		Fax:	
E-Mail:		Website:	
Contact person:			
The company was founded in: (month/year)		Number of staff: (as of 12/31/07)	
Kind of laboratory:	☐ none ☐ chemical/analytical ☐ biological/L1/S1 ☐ L2/S2 ☐ L3/S3		

2. BIOTECHNOLOGY ACTIVITIES / TECHNIQUES

Please indicate your firm's activities in 2007 for each of the biotechnology techniques listed below. (Check all that apply):		active	not active
DNA/RNA: genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, use of antisense technology, RNA technology.		☐	☐
Proteins and other molecules: sequencing/synthesis/engineering of proteins and peptides, proteomics, protein isolation and purification, signal transduction, identification of cell receptors, improved delivery methods for large molecule drugs		☐	☐
Cell and tissue culture and/or engineering: cell/tissue culture, tissue engineering, cellular fusion		☐	☐
Process biotechnology techniques:	fermentation, enzyme catalysis	☐	☐
	bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation	☐	☐
Gene and RNA vectors: gene therapy, viral vectors		☐	☐
Systems biology / bioinformatics: construction of databases on genomes or protein sequences; modelling complex biological processes		☐	☐
Nanobiotechnology: application of nano/microfabrication tools and processes to build devices for studying biosystems and applications in drug delivery and diagnostics		☐	☐
Other (please specify):		☐	☐

3. BIOTECHNOLOGY PRODUCTS AND COMPANY STRATEGY

A biotechnology product can be either a good or service. Its development must have required the use of one or more of the biotechnologies listed in Section 2. A biotechnology process is defined as a production or other process that employs one or more biotechnology techniques or products.	**YES**	**NO**
Did your firm have biotechnology products on the market in 2007?	☐	☐
Is your firm currently developing products that are dependent on the use of biotechnology?	☐	☐
Is your firm currently developing processes that require the use of biotechnology?	☐	☐
Do you consider biotechnology to be central to your firm's activities or strategies?	☐	☐

4. BIOTECHNOLOGY SEGMENT

Please indicate your firm's biotechnology activities for the following applications
Check the squares that apply and fill in the numbers in those rows

		Not active	**R&D**	**Product development**			**Services**
Human health/ medicine	High molecule therapeutics, biopharmaceuticals, recombinant monoclonal antibodies, DNA and RNA therapeutics, vaccines, etc.	☐	☐	**Phase I & II** ☐ Number of ▽	**Phase III & NDA** ☐ Number of ▽	**Approved** ☐ Number of ▽	☐
	Chemically synthesized and other therapeutics, etc.	☐	☐	☐ Number of ▽	☐ Number of ▽	☐ Number of ▽	☐
	Diagnostics	☐	☐	**Regulatory phase** ☐ Number of ▽		**Approved** ☐ Number of ▽	☐
	Cell and tissue culture, tissue engineering	☐	☐	☐ Number of ▽		☐ Number of ▽	☐
Animal health/ medicine	All health applications for animals	☐	☐	☐ Number of ▽		☐ Number of ▽	☐
Agriculture	Non-GM plants, animals, micro-organisms or pest control developed using biotechnology techniques (DNA markers, tissue culture, etc.)	☐	☐	**Confined trials** ☐	**Release trials** ☐	**Marketed / in production** ☐	☐
	GM plants, animals and micro-organisms for use in agriculture, aquaculture, and silviculture, etc.	☐	☐	☐	☐	☐	☐
Industrial processing	Bioprocessing techniques used in production (plastics, ethanol, chemicals, food) or for the transformation of inputs, etc.	☐	☐	**Marketed / in production** ☐			☐
Environment	Diagnostics, bioremediation of soil, treatment of water, air, and industrial effluents using micro-organisms, etc.	☐	☐	☐			☐
Natural resource extraction	Applications in mining, extraction of fossil fuels, etc.	☐	☐	☐			☐
Bioinformatics	Construction of databases on genomes, protein sequences; modelling complex biological processes	☐	☐	☐			☐

Please note: all information submitted in Sections 5-7 (marked with an *) will be handled in strict confidence. It will be evaluated anonymously, and will not be published. The data accumulated will be used exclusively for analyses by the BMBF. The aggregate results of this biotechnology company survey will be made available to all of the participating biotech companies free of charge by May of 2008.

5. EMPLOYMENT

How many employees did your company have on the 31st of December 2007? (Both in Germany and abroad)	
*How many employees did your company have on the 31st of December 2007 in Germany?	
* How many employees did your company have on the 31st of December 2007 who spent most or all of their working hours on biotechnology activities (see Section 2)? *Please include: researchers, management, technical and administrative staff who were directly involved in biotechnology activities.*	
* From your biotechnology employees in 2007, how many were primarily engaged in... – R&D? – production? – other?	
* From your biotechnology employees in 2007, how many have a university degree?	

6. FINANCIAL CHARACTERISTICS (IN EUROS)

* Total value of sales / revenues in 2007:	€
* Value of revenues from biotechnology activities in 2007:	€
* Total R&D spending in 2007:	€
* R&D spending on biotechnology activities in 2007:	€
* How much venture capital did your company raise for biotechnology activities in 2007?	€
* To what extent does venture capital contribute to your company's equity (in %)?	%
* What is the total amount in government grants that your company received for biotechnology activities in 2007?	€

7. BIOTECHNOLOGY PRODUCTION

	YES	**NO**
* Does your company operate a production facility? **(If "No", please proceed directly to Section 8).**	☐	☐
* Is a clean room according to ISO 14644 part of the facility?	☐	☐
* Does your company produce its own products in the facility?	☐	☐
* Does your company offer service production for third parties?	☐	☐
* Does your company produce biopharmaceuticals in its own facility?	☐	☐
* If yes, what is the plant's installed fermentation capacity?	.....	
* Does your company produce low molecular weight therapeutics ("small molecules") in its own facility?	☐	☐

*** This information will be evaluated anonymously, and will not be either passed on or published.**