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Biotechnology Statistics in OECD Member Countries: An Inventory

Brigitte van Beuzekom

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BIOTECHNOLOGY STATISTICS IN OECD MEMBER COUNTRIES: AN INVENTORY

STI WORKING PAPER 2004/8 Statistical Analysis of Science, Technology and Industry

Brigitte van Beuzekom

In some cases, the biotechnology or R&D questionnaires used by national statistical offices are also available. To download these annex documents, go to: http://www.oecd.org/sti/working-papers.

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BIOTECHNOLOGY STATISTICS IN OECD MEMBER COUNTRIES: AN INVENTORY

Brigitte van Beuzekom

Abstract

This document reflects recent efforts made by the OECD to obtain an accurate assessment of the current state of biotechnology statistics in OECD member and observer countries. It is an update of the original document, which was released in 2000.

The inventory was prepared by Brigitte van Beuzekom of the OECD's Directorate for Science, Technology and Industry, and benefited from contributions of the delegates involved in the OECD Ad hoc Meeting on Biotechnology Statistics. Comments are welcome and should be sent by e-mail to Brigitte van Beuzekom [e-mail: brigitte.vanbeuzekom@oecd.org].

STATISTIQUES DE LA BIOTECHNOLOGIE DANS LES PAYS MEMBRES DE L'OCDE : INVENTAIRE

Brigitte van Beuzekom

Abstract

Ce document reflète les récents efforts de l'OCDE pour établir un état des lieux précis de la disponibilité des statistiques de la biotechnologie dans les pays membres de l'OCDE et dans les pays observateurs. Il s'agit d'une mise à jour du document paru en 2000.

Cet inventaire a été préparé par Brigitte van Beuzekom de la direction de la Science, de la Technologie et de l'Industrie de l'OCDE, avec les contributions des délégués impliqués dans la réunion Ad hoc sur les statistiques de la biotechnologie. Tous commentaires sont les bienvenus et devront être adressés par mél à Brigitte van Beuzekom [Courriel: brigitte.vanbeuzekom@oecd.org].

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BACKGROUND

This Working Paper summarises the information gathered by the Secretariat as part of its work to obtain an accurate assessment of the current state of biotechnology statistics in OECD member and observer countries. It is an update of the original document, which was released in 2000. The updated inventory reveals a marked increase in the number of countries collecting biotechnology data since 2000. In 2004, 27 countries collect such data, or intend to in the near future, compared to 14 countries in 2000. Further, national statistical offices dominate the data collection scene in 2004, whereas in 2000, biotechnology data was predominantly available from non-official sources (consulting agencies, etc). This shift is likely due to demands made by national policy makers.

Before the OECD undertook its work on biotechnology statistics in 2000, there was no internationally agreed upon statistical definition of biotechnology. In 2001, as a result of the work done by the Ad hoc Meeting on Biotechnology Statistics, OECD countries came to a consensus on a statistical definition of biotechnology. In 2004, 18 countries have adopted the OECD statistical definition of biotechnology. The Ad Hoc Meeting on Biotechnology Statistics has also developed concepts and definitions for statistical purposes and set forth guidelines for the compilation of biotechnology indicators, including model questions for inclusion in national surveys.

This inventory has been compiled on the basis of information provided by officials in member and observer countries (or Organisations). It also identifies situations where no information has been made available and where notification has been received that no such data exists in a country. In the latter case, the contact details of the respondent have been included for future reference.

The country profiles were developed using a standard format. A separate entry has been made for each data source in each of the countries covered by the exercise. The standard format includes details of the agency involved, a description of the collection or compilation in terms of its type, the data items included, its coverage, the frequency with which data have been (or are intended to be) collected, the time period for which data are available, the definitions and classifications used, and the availability of published information. The format also includes a reference to the most appropriate Web sites at which additional information may be available.

In some cases, the biotechnology or R&D questionnaires used by national statistical offices are included. To download these annex documents go to: <u>http://www.oecd.org/sti/working-papers</u>.

Table 1 summarises the availability of data reported in this paper and is intended to serve as a ready reference.

	OFFICIAL DATA: 2000			OFFICIAL DATA: 2004			
	Biotech Firm Survey	R&D survey	No Data	Biotech Firm Survey	R&D survey	OECD definition	No Data
Australia		x		X Future	Х	Х	
Austria			х				Х
Belgium			х	Х		Х	
Canada	х	х		X	Х	Х	
Czech Republic			х		X Future	X Future	
Denmark		х			Х		
Finland			х	-	Х	Х	
France	х			Х	Х	Х	
Germany		Onetime survey ('92)		Х		Х	
Greece	No	information provided	d		X (GOVT)		
Hungary			х		X Future		
Iceland		x ('99)		X R&D		Х	
Ireland			х		Х	Х	
Italy		x			Х	Х	
Japan	х	x		Х	Х		
Korea	No information provided		d	Х	X (GOVT)		
Luxembourg	No	information provided	d	No infe	ormation pro	vided	
Mexico			х		No information provided		
Netherlands		x					Х
New Zealand	х			Х		Х	
Norway		х		X R&D	Х	Х	
Poland			x		X X (GOVT)	х	
Portugal		x					Х
Slovak Republic			х		X Future	X Future	
Spain			х	X Future		Х	
Sweden			х		Х	X Future	
Switzerland		x			Х	Х	
Turkey	No	information provided	d				Х
United Kingdom		x (GOVT)		Х	X (GOVT)		
United States			х	Х	Х		
China				Х			
Israel			х	Х		Х	
South Africa			х	Х			
European Commission				-	x		
EUROSTAT			_	-	X X (GOVT)		

Table 1. Summary of available biotechnology statistics

X Future: Country to carry out survey in the near future; Govt: Only for Government Budget Appropriations or Outlays for R&D collected; X R&D: special surveys for R&D performers. Source: OECD.

COUNTRY PROFILES

1. AUSTRALIA

Collection/compilation agency: Australian Bureau of Statistics (ABS)

Collection/compilation type: R&D Survey.

Variables: R&D expenditure.

Scope: Business enterprise sector.

Frequency: Survey in respect of 2001-02.

Periodicity: Onetime.

Classification used: A question asking for percentage of R&D expenditure attributable to biotechnology.

Definition used: OECD definition of biotechnology.

Output: Paper prepared for discussion at the OECD 5th Ad hoc Meeting on Biotechnology Statistics, 2004.

Contact comments: Responses to the biotechnology question were linked to reported fields of science in an attempt to identify fields of science relevant to biotechnology.

Future plans (plans for new collections, strategies, experiences, etc.): A biotechnology firm survey in respect of 2003-04 is currently being developed.

Contact details: http://www.abs.gov.au

Survey attached in annex

2. AUSTRALIA

Collection/compilation agency: Department of Industry, Tourism and Resources (ITR) in association with AusBiotechnology and consultants - Ernst & Young, Advance Consulting & Evaluation Pty Ltd and Aoris Nova Pty Ltd.

Collection/compilation type: The Directory was produced in association with AusBiotech. The Australian Biotechnology Reports were jointly produced by Ernst & Young and ITR and follow the style of reports produced by Ernst & Young overseas (*e.g.* for Canada).

The statistics for the Global Partners Report were prepared by Consultants (Advance Consulting & Aoris Nova) who maintain a database of biotechnology firms and activities in accordance with the OECD definition. The database is maintained through publicly available information sources and ad hoc industry surveys which were not prepared in consultation with the Government.

Variables: N/A

Scope: Any company, public or privately held, which is developing or commercialising biotechnology related products, or who provided expertise and supplies to biotechnology companies as a significant component of their business. Excluded are: not-for-profit enterprises, research institutions and corporate structures which are established for the purposes of administering research grant funds but have no commercial intent.

Frequency: Studies in respect of 1999, 2001 and 2004.

Periodicity: N/A

Classification used: N/A

Definition used: The 1999 and 2001 reports defined biotechnology as "the application of all natural sciences and engineering in the direct or indirect use of living organisms, or parts of organisms, in their natural or modified forms, in an innovative manner in the production of goods and services" and noted that "biotechnology was used in the areas of therapeutics, foodstuffs, devices, diagnostics, etc. and/or to improve existing industrial processes. The market application of outputs is typically in the general areas of human health, food production, industrial bio-processing and other public good and environmental settings".

The 2004 report adopts the OECD definition of biotechnology defining it as "the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services".

Biotechnology techniques may be applied to different economic sectors. This report groups these sectors as follows:

- Human therapeutics, including development of biotech-derived drugs.
- Biotechnology-based diagnostic products and services to identify human disease.
- Agribiotech, encompassing the use of biotechnology for development and delivery of products and services aimed at the agricultural sector.

- Foods and beverages, encompassing the use of biotechnology for development of new foods (including functional foods) and food additives.
- Chemical, environment and other sectors, encompassing the use of biotechnology in mining, chemical development, and the environment; and
- Suppliers of molecular biologicals, such as monoclonal antibodies, diagnostic reagents and gene chips.

Output:

Australian Biotechnology Directory

Ernst & Young, Australian Biotechnology Report 1999, and Australian Biotechnology Report 2001

Global Partners, Australian Biotechnology 2004 (to be published in June 2004)

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences, etc.): N/A

Contact details:

http://www.industry.gov.au http://www.ausbiotech.org http://www.biotechnology.gov.au

3. AUSTRALIA

Collection/compilation agency: Aoris Nova Pty Ltd and Advance Consulting & Evaluation Pty Ltd

Collection/compilation type: Annual reviews of biotechnology industry trends.

Variables:

- Number of private and public companies by year, sector, employment
- Numbers of alliances
- Numbers of patents to Australian inventors
- Numbers of new stock exchange listings
- List of new firms formed
- Approvals by the regulator
- Performance of Australian listed companies
- Lists of grantees and investees in the collection period
- Also includes information on medical devices in some issues, service providers to the biotechnology industry and investors.

Scope: Australia and New Zealand, discusses trends as well as providing statistics.

Frequency: Annual.

Periodicity: December.

Classification used: N/A

Definition used: OECD definition of biotechnology.

Output:

2001 Australian Bioindustry Review

2002 Bio-Industry Review, Australia and New Zealand

2003 Bio-Industry Review, Australia and New Zealand

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences, etc.): Considering global industry comparisons and new issuing schedule.

Contact details: Dr. Kelvin Hopper, Aoris Nova, <u>Khopper@aoris.com.au</u>; Dr. Lyndal Thorburn, <u>Lyndal@advanceconsulting.com.au</u>

Surveys attached in annex

Surveys sent to new firms 2002/03:

- Survey of service providers •
- Survey of Australian biotechnology firms formed in 2002/03 survey of NZ biotechnology firms formed in 2002/03 •

AUSTRIA

Collection/compilation agency: Austrian Central Statistical Office

Comments: No data on biotechnology are collected.

Contact details: <u>http://www.oestat.gv.at/</u>

BELGIUM

Collection/compilation agency: The biotechnology survey is an initiative of the *Office for Scientific Technical and Cultural Affairs (Federal Science Policy).* The Limburgs Universitair Centrum (Center for Statistics, ITEO), the University of Liege (CRGB) and Vlerick Management school are responsible for the practical organisation of the survey (data collection and analyses).**Collection/compilation type:**

- Survey: Use and Development of Biotechnology, 2003
- Semi structured interviews with managers and players on the financial side.

Variables:

- General company information
- Use and development of biotechnology (7 broad categories)
- What biotechnology expertise is the core technology?
- Human resources in biotechnology
- Innovative activities:
 - Development of products or processes? (7 broad categories)
 - Products of processes on the market?
 - Patents and licenses
- Factors influencing the use and/or development of biotechnology (list of 17 factors)
- Financial profile.

Scope: Biotechnology firms and research laboratories (public and universities).

Frequency: 2003 (2004 ongoing).

Periodicity: Annual.

Definition used: OECD definition of biotechnology. "Biotechnology refers to the application of R&D to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services".

As a means to evaluate the definition above a list with activities was provided. The activities that were applicable had to be crossed.

- DNA- the coding
- Proteins and Molecules the functional blocks
- Cell/tissue culture, Embryo manipulation
- Process Biotechnologies
- Sub-Cellular Organisms
- Bioinformatics
- Other

Classification used: See definition used.

Output: The final report is expected to be released in 2004.

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): The planning of the biotechnology survey for 2004 is ongoing.

Contact details:

Federal Science policy: <u>http://www.belgium.be/eportal/</u> Limburgs Universitair Centrum: <u>http://www.luc.ac.be</u> Ulg: <u>http://www.ulg.ac.be/</u> Vlerick Management School: <u>http://www.vlerick.be/</u>

Survey attached in annex

Collection/compilation agency: Statistics Canada

Collection/compilation type: Annex on biotechnology activities to the Federal Scientific Expenditures and Personnel Survey.

Scope: Government.

Variables:

- Aggregate Federal Government S&T Expenditures on Biotechnology by Activity and Performer
- Federal Government S&T Expenditures on Biotechnology Activities, by selected Government Department or Agency and Performer
- Federal Government R&D Expenditures on Biotechnology Activities, by selected Government Department or Agency and Performer
- Federal Government S&T Expenditures compared to Biotechnology Expenditures, by selected Government Department or Agency and Performer
- Federal Government R&D Expenditures compared to Biotechnology Expenditures, by selected Government Department or Agency and Performer.

Frequency: Annual.

Collection/compilation agency: Statistics Canada

Collection/compilation type: Research and Development in Canadian Industry Survey.

Sector covered: Industry.

Variables:

- Biotechnology R&D expenditures
- Source of Funds: Government, national sources, foreign sources (Although not biotech specific)
- Division between capital and current expenditures (Although not biotech specific)
- R&D by sector (5 sectors).

Frequency: Annual.

Future plans (plans for new collections, strategies, experiences, etc.): N/A

The following section covers three *ad hoc* surveys specific to biotechnology implemented by Statistics Canada.

Collection/compilation agency: Statistics Canada

Collection/compilation type: Survey of Biotechnology Use in Canadian Industries - 1996.

Variables:

- Company information: operating revenue, sales, exports, employees
- Biotechnologies used: 22 biotechnologies, used in operations (yes/no), number of years in use, utilisation stage (4 choices), plan to use in next two years (yes/no), no plans to use (2 reasons)
- Capital investment in biotechnology equipment: cost category 6 by 3
 - 1. Selection and/or Modification of Biological Material
 - 2. Culture and/or Use of Biological Material
 - 3. Environmental Biotechnologies
- Ranking of positive influences associated with adoption of biotechnologies (9 categories)
- Ranking of difficulties experienced by firms in implementing biotechnologies (11 categories)
- Ranking of benefits associated with adoption of biotechnologies (15 categories)
- Ranking of impediments to biotechnology acquisition (20 categories)
- Sources of information (internal and external: 14 categories)
- Ranking of production technology vis-à-vis other Canadian producers and Producers abroad
- Information on alliances in Canada and abroad.

Reference year: 1996.

Periodicity: Occasional.

Output:

Working Paper ST-98-05, *Biotechnology Use by Canadian Industry*, *1996*, Antoine Rose, March 1998 http://www.statcan.ca/english/research/88F0006XIB/88F0006XIB1998005.pdf

Research Paper No. 6, *Diffusion of Biotechnologies in Canada*, Anthony Arundel, February 1999 <u>http://www.statcan.ca/english/research/88F0017MIE/88F0017MIE99006.pdf</u>

Collection/compilation type: Biotechnology Firm Survey – 1997.

Variables:

- Company information: biotechnology activities (yes/no)
- Biotechnologies used: 22 biotechnologies, used in operations (yes/no), principal use (3 choices), plan to use in next three years (yes/no)
- Choice of three bio-industry sectors that best describe firms activities (22 choices)
- Use new process in the last 3 years (yes/no)
- Plan to use new process in the next 3 years (yes/no)
- Company financial information: public/private, balance sheet, revenue, expense, exports, employees, sales
- R&D expenditures: (yes/no), applied for tax benefit (yes/no) if no why not (4 choices)
- Strategic alliances (choice of 13 reasons): yes/no, with Canadian partner or US, EU, Asia, South/Latin America, Other
- Human resources in biotech activities (choice of 7 positions): employed, unfilled, estimated employed in 2001
- Human resources: Education & training programme (yes/no) estimate expenditures
- Human resources: Co-op programs students from universities employed (yes/no)
- Full-time person employed for human resources (yes/no)
- Estimated staff turnover rate
- Problems recruiting business operations staff (yes/no) if yes choice of 4 specialities
- Problems recruiting technical/production/scientific/R&D staff (yes/no) if yes choice of 3 specialities
- Hired personnel from outside Canada (yes/no) if yes which areas (choice of 5) if yes successful (yes/no) if no why (4 reasons)
- Had to abandon biotech project because of IP rights (yes/no), if yes patent in Canada (yes/no)
- Litigation related to patent infringement (yes/no), if yes number of cases
- During last three years has firm *assigned* the right to use IP (four options) in Canada, outside Canada
- During last three years has firm *acquired* the right to use IP (four options) in Canada, outside Canada
- Problems for biotech commercialisation in Canada (choice of 3 issues amongst 6) and 5 types of regulations issues.
- Financing: Capital raised (yes/no), if yes: how much. Purposes (choice of 4). Sources (choice of 7) Plan to raise capital? (yes/no), if yes: how much. Purposes (choice of 4). Sources (choice of 7)
- Strategic decisions: Most important decisions made in 1997 and 1998 18 choices.

Reference year: 1997.

Periodicity: Occasional.

Comments: So far, each of the biotech surveys was occasional. However, with the last survey, this may be beginning to stabilise and some more regular periodicity may be foreseen.

Industrial Classification used: See the following table. This *ad hoc* classification was developed to distribute firms across biotechnology application sectors

Category: Human Health - Bio	Category: Food Processing	Category: Forest Products
1. Diagnostics (<i>e.g.</i> immunodiagnostics, gene probes, biosensors)	9. Bioprocessing (<i>e.g.</i> using enzymes and bacteria culture)	16. Silviculture (<i>e.g.</i> ectomycorrhizae, tissue culture, somatic embryogenesis, genetic markers, genetic engineering)
2. Therapeutics (<i>e.g.</i> vaccines, immune stimulants, Biopharmaceuticals, rational drug design, drug delivery, combinatorial chemistry)	10 Functional Foods/Nutriceuticals (<i>e.g.</i> probiotics, unsaturated fatty acids)	17. (Cleaner) Industrial Bioprocessing (<i>e.g.</i> biopulping, biobleaching, biological prevention of sapstain)
3. Gene Therapy (<i>e.g.</i> gene identification, gene constructs, gene delivery)	Category: Aquaculture	Category: Environment
Category: Bio-Informatics	11. Fish health (<i>e.g.</i> diagnostics, therapeutics)	18. Biofiltration (<i>e.g.</i> treatment of organic emissions to air/water)
4. Genomics and Molecular Modelling (e.g. DNA/RNA/protein sequencing & databases for humans, plants, animals and micro-organisms)	12. Broodstock genetics (e.g. tracking superior traits, genetic modification / engineering)	19. Bioremediation and Phytoremediation (<i>e.g.</i> cleanup of toxic waste sites using micro-organisms)
Category: Ag - Bio	13. Bioextraction (<i>e.g.</i> karageenan from seaweed, antifreeze proteins from fish, flavours)	20. Diagnostics (<i>e.g.</i> detection of toxic substances using bioindicators, biosensors, immunodiagnostics)
5. Plant Biotechnology (<i>e.g.</i> tissue culture, embryogenesis, genetic markers, genetic engineering)	Category: Mining/Energy/Petroleum/Chemicals	Category: Other
 Animal Biotechnology (e.g. diagnostics, therapeutics, embryo transplantation, genetic markers, genetic engineering) 	14. Microbiologically enhanced petroleum/mineral recovery	21. Custom synthesis- chemical or biological (<i>e.g.</i> peptides, proteins, nucleotides, hormones, growth factors, biochemicals
7. Biofertilizers/Biopesticides/ Bioherbicides/Biological Feed Additives/Microbial pest control (<i>e.g.</i> bacteria, fungi, yeasts)	15. (Cleaner) Industrial Bioprocessing (<i>e.g.</i> biodesulphurization, bio-cracking, bio-recovery)	22. Other (please specify)
8. Non-Food Applications of Agricultural Products (<i>e.g.</i> fuels, lubricants,commodity and fine chemical feedstocks, cosmetics)		

Definition used: Rather than defining biotechnology Canada has established a list of 22 biotechnologies. A firm becomes a biotechnology user when it uses at least one biotechnology from a list of biotechnology activities. The list for the Biotechnology Firm Survey - 1997 is the following:

DNA Based	Genetic Engineering
	Gene Probes
	Bio-informatics/Genomics/Pharmacogenetics
	DNA Sequencing/Synthesis/Amplification
	Gene Therapy
Biochemistry/Immunochemistry Based	Vaccines/ Immune Stimulants/Drug Design & Delivery/Combinatorial Chemistry
	Diagnostics Tests/Antibodies
	Peptide/Protein Sequencing or Synthesis
	Cell Receptors/Cell Signalling/Pherormones/Three Dimensional Molecular
	Modelling/Structural Biology
	Biosensors
	Biomaterials
	Microbiology/Virology/Microbial Ecology
Bioprocessing Based	Cell/Tissue/Embryo Culture & Manipulation
	Fermentation/Bioprocessing/Biotransformation/Bioleaching/Biopulping/
	Biobleaching/Biodesulphurization
	Extraction/Purification/Separation
	Bioremediation/Phytoremediation/Biofiltration/Bioindicators
	Natural Product Chemistry

Collection/compilation type: Biotechnology Use and Development Survey – 1999.

Variables:

- Biotechnologies used: 22 biotechnologies, used in operations (yes/no), principal use (3 choices), plan to use in next three years (yes/no)
- If firm does not use biotechnology ranking of barriers to using (12 categories)
- Ranking of sources of information (internal and external: 12 categories)
- Ranking of benefits associated with adoption of biotechnologies (13 categories)
- Human resources in biotech activities: number of employees, number of employees with biotechrelated responsibilities
- Human resources in biotech activities (choice of 7 positions): full-time, part-time, estimated employed in 2002
- Human resources in biotech activities (choice of 7 positions): unfilled full-time and choice of three
 options for the reason
- Does your firm employ (either paid or unpaid) post-secondary students in biotechnology-related activities? Include co-op placements, part-time, and full-time positions (yes/no) – if yes: level of education (choice of three)
- Does your firm contract out any of the following biotechnology-related activities? (yes/no) (4 activities) if yes: value of contracts?
- Recruiting Practices: methods used to fill biotechnology-related positions (choice of 11)
- Hired personnel from outside Canada (yes/no) if yes which areas (choice of 5) if yes successful (yes/no) if yes how many
- Did biotechnology personnel leave your firm in 1999?
- Product/Process Development: Is your firm currently developing product that requires the use of biotechnologies? (yes/no)
- Is your firm currently developing processes that requires the use of biotechnologies? (yes/no)
- Does your firm consider biotechnology central to its activities? (yes/no)
- Biotechnology Products: Please provide the number of biotechnology products or processes your firm has at each stage of development. (Industrial Classification list similar to the one above) and by Number of biotechnology products/processes by development stage (choice of 4)
- Was your firm involved in biotechnology-related co-operative/collaborative arrangements with other companies or organizations? (yes/no) if yes how many
- For what purpose? (choice of 8 arrangement purposes)
- By geographic location: with Canadian partner or USA, EU, Asia, South/Latin America, Other and Partner category (5 types)
- Would you describe your firm as a "spin-off"? (yes/no) if yes from (choice of 4)
- Ranking of Obstacles to Biotechnology Commercialization (15 choices)
- Patents: Existing and Pending by Geographic location
- Patent applications choice of three patent offices and other

- Number of applications for plant breeders' rights your company submitted choice of three offices and other
- During last two years has firm assigned or acquired the right to use IP (four options) in Canada, outside Canada (three types of IP)
- Company information: operating revenue, sales, exports, imports
- Biotech Exports to what geographic locations (choice of 5)
- Biotech Imports from what geographic locations (choice of 5)
- Attempt to raise capital (yes/no) if yes source of capital (choice of 7)
- Intention to raise capital in 2002 (yes/no) if yes how much (choice of 3)
- Apply for tax benefit in past 5 years (yes/no) if no why not (choice of 4)
- Does your firm use Internet (yes/no) if yes for what purposes (choice of 9)
- Strategic decisions: 14 choices.

Reference Year: 1999.

Periodicity: Occasional.

Output:

Working Paper ST-01-07, *Biotechnology Use and Development, 1999*, Chuck McNiven, March 2001 <u>http://www.statcan.ca/english/research/88F0006XIB/88F0006XIB2001007.pdf</u>

Working Paper ST-01-11, Practices and Activities of Canadian Biotechnology Firms: Results from the Biotechnology Use and Development Survey - 1999, Chuck McNiven, August 2001 http://www.statcan.ca/english/research/88F0006XIB/88F0006XIB2001011.pdf

Working Paper ST-02-03, Use of Biotechnologies in the Canadian Industrial Sector: Results from the Biotechnology Use and Development Survey - 1999, Chuck McNiven, March 2002 http://www.statcan.ca/english/research/88F0006XIB/88F0006XIE2002003.pdf

Working Paper ST-02-04, Profile of Spin-off Firms in the Biotechnology Sector: Results from the Biotechnology Use and Development Survey - 1999, Craig Byrd, March 2002 http://www.statcan.ca/english/research/88F0006XIB/88F0006XIE2002004.pdf

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details:

http://www.statcan.ca/english/research/scilist.htm - For papers and the survey for greater detail.

http://www.statcan.ca/francais/research/scilist_f.htm - French version.

http://strategis.ic.gc.ca

Collection/compilation type: Survey of Biotechnology Use in Canadian Industries - 2001

Variables:

- Biotechnologies used: 22 biotechnologies, used in operations (yes/no), principal use (3 choices), number of years in use, plan to use in next three years (yes/no)
- If firm does not use biotechnology return the questionnaire
- The effects of biotechnology on your firm: The level of influence of each factor on increasing your use of biotechnology (5 degrees), the level of impacts of biotechnology use on your firm's performance (5 degrees)
- Human resources in biotech activities: number of employees, number of employees with biotechnology-related responsibilities, number of full-time biotechnology employees (7 positions and total), number of part-time biotechnology employees (7 positions and total)
- Recruiting practices: unfilled biotechnology-related positions (yes/no), if yes: the number of unfilled positions by category (choice of 7 positions)
- Recruiting practices: Did you attempt to recruit any biotechnology employees in 2001?(yes/no), if yes, successful (yes/no), if yes, number of employees, sources used in recruiting (choice of 11)
- The impact of factors on your efforts in filling biotechnology-related vacancies (choice of 7)
- Hired personnel from outside Canada (yes/no), if yes successful (yes/no) if yes how many
- Human resources in biotech activities: Did biotechnology personnel leave your firm in 2001? (yes/no)-if yes, number of biotechnology personnel that left
- Biotechnology products: Do you have biotechnology product/process on the market? (yes/no), if yes, what year was the most significant product first introduced?
- Biotechnology products: Is your firm currently developing products that require the use of biotechnologies? (yes/no), if yes, what year will the most significant of these products reach market?
- Is your firm currently developing processes that require the use of biotechnologies? (yes/no) if yes, what year will the most significant of these processes be completed?
- Does your firm consider biotechnology central to its activities? (yes/no)
- Biotechnology Products: Please provide the number of biotechnology products or processes your firm has at each stage of development. (Industrial Classification list similar to the one above) and by Number of biotechnology products/processes by development stage (choice of 4)
- What is the total time required to bring your principal biotechnology product or process from the initial development phase/proof of concept stage to the market? What is the total cost to bring it to the market?
- Business practices: Did your firm contract out biotechnology related activities in 2001? (yes/no), if yes, type of partner (private/public), numbers of contracts and total value of contract in 2001 by purpose of contract (choice of 4)
- Did you contract out to organizations outside of Canada? (yes/no), if yes, indicate the percentage (%) of your firm's total contracting out by organization (choice of 5)
- Business practices: level of importance of each of the following reasons on your decision to contract out (choice of 8 reasons and 5 degrees)

- Does your firm provide contract services to other firms or organizations (yes/no); if yes number of contracts entered in 2001, revenue received and sources of the contract (choice of 5 sources)
- Was your firm involved in biotechnology-related cooperative/collaborative arrangements with other companies or organizations? (yes/no) if yes number of arrangements by partner type (choice of 4) and by arrangement purpose (choice of 8)
- Intellectual property: Did your firm grant biotechnology related intellectual property rights to another firm? (yes/no) if yes the number of IP rights by type of IP (choice of 3 IP instruments) and by country (choice of 3); Revenue from IP licensing in 2001
- Did your firm obtain biotechnology related intellectual property rights from another firm? (yes/no) if yes, the number by type of IP and by country; Cost to your firm of obtaining IP in 2001
- Patents: Existing and Pending by Patent office, number of unique patent applications your company submitted in 2000 and 2001
- Firm characteristics and financial profile: revenue, research and Development expenditures and % of biotechnology R&D spending contracted out in 2000 in 2001 and forecast of 2004
- Sales of biotechnology products (yes/no), if yes, percentage of your sales by type of clients (choice of 2)
- Firm history: Is your firm a public firm? (yes/no), if yes, what year was the Initial Public Offering?
- What year was your firm or spin-off established?
- Merger with another firm (yes/no), if yes, what year
- Is your firm a subsidiary of a multinational enterprise?
- Is your firm a spin-off? (yes/no), if yes, from (choice of 5)
- Attempt to raise capital (yes/no) if yes how much, target reached (yes/no) if no, reasons given by lender (choice of 7), source of funding (choice of 7)
- The main product or process: Current stage of development (choice of 4), total spending and spending by stage of development, total amount of the capital required to complete each stage
- How long do you anticipate this capital? (In years and months)
- Reasons for raising/attempting to raise capital (6 choices)
- Do you plan to raise capital in 2002 (yes/no), if yes how much (choice of 3)
- Apply for tax benefit in past 5 years (yes/no), if yes, how much, if no why not (choice of 4), have any of your SR&ED credits expired? (yes/no)
- Apply for provincial R&D tax benefit or incentive?(yes/no), if no, reasons (choice of 4)
- Exports (yes/no) if yes, value and percentage of exports, by geographic location (choice of 4) for 2000, 2001 and a 2004 forecast
- Imports (yes/no), if yes, value and percentage of imports, by geographic location (choice of 4) for 2000, 2001 and a 2004 forecast
- Strategies used in 2001 (12 choices of strategies and 5 degrees)
- Development, production or sale of Living Modified Organisms (yes/no), if yes, how many, by stages (choice of 3)
- Exports of LMO (yes/no), if yes, how many and geographic location (choice of 3)

Reference year: 2001.

Periodicity: Occasional.

Output:

Working Paper ST-03-05, *Features of Canadian Biotech Innovative Firms: Results from the Biotechnology* Use and Development Survey - 2001, Chuck McNiven, Lara Raoub and Namatié Traoré, March 2003 http://www.statcan.ca/english/research/88F0006XIB/88F0006XIE2003005.pdf

Working Paper ST-03-13, *Bioproducts Development by Canadian Biotechnology Firms: Findings from the 2001 Biotechnology Use and Development Survey*, Namatié Traoré, December 2003 http://www.statcan.ca/english/research/88F0006XIB/88F0006XIE2003013.pdf

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details:

http://www.statcan.ca/english/research/scilist.htm - For papers and the survey for greater detail.

<u>http://www.statcan.ca/francais/research/scilist_f.htm</u> – French version.

http://strategis.ic.gc.ca

Survey attached in annex

Collection/compilation type: Survey of Biotechnology Use in Canadian Industries - 2003

Variables:

- Biotechnologies used: 9 biotechnologies, used in operations (yes/no), principal use (3 choices), number of years in use, plan to use in next three years (yes/no)
- If firm does not use biotechnology go to section 7: bioproducts
- Human resources in biotechnology activities: number of employees in Canada, number of employees with biotechnology-related responsibilities, number of full-time biotechnology employees (7 positions and total), number of part-time biotechnology employees (7 positions and total)
- Recruiting practices: unfilled biotechnology-related positions (yes/no), if yes: the number of unfilled positions by category (choice of 7 positions)
- Recruiting practices: Did you attempt to recruit any biotechnology employees in 2003 ?(yes/no), if yes, successful (yes/no), if yes, number of employees
- Recruiting practices: Did you attempt to recruit any biotechnology employees from outside of Canada in 2003?(yes/no), if yes, number of employees hired by country/region
- The impact of factors on your efforts in filling biotechnology-related vacancies (7 factors)
- Human resources in biotech activities: Did biotechnology personnel leave your firm in 2003? (yes/no)-if yes, number of biotechnology personnel that left
- Firm history: what year was your firm established? Is your firm a public firm? (yes/no), if yes, what year was the Initial Public Offering?
- Merger with another firm (yes/no), if yes, what year?
- Is your firm a subsidiary of a Multi-National enterprise?
- Is your firm a spin-off? (yes/no), if yes, from: (choice of 5)
- Biotechnology products: Do you have biotechnology product/process on the market? (yes/no)
- Is your firm currently developing products that require the use of biotechnologies? (yes/no)
- Is your firm currently developing processes that require the use of biotechnologies? (yes/no)
- Does your firm consider biotechnology central to its activities? (yes/no)
- Biotechnology: number of biotechnology products/processes by development stage (choice of 4) and by sector (17 categories)
- Did you have biotechnology products or processes in any stage of R&D? (yes/no), if yes, number of products or processes
- Principal product or process: current stage of development (choice of 3), how long has it been under development? (in years and months), how much did you invest in R&D ?
- Did you have any biotechnology products or processes in production or on the market? (yes/no) if yes, number of products or processes. What is the total time required to bring your principal biotechnology product or process from the initial development phase/proof of concept stage to the market? (in years and months) What is the total cost to bring it to the market?
- Business practices: Did your firm contract out biotechnology related activities in 2003? (yes/no), if yes, type of partner (choice of 5), number of contracts and total value of contract in 2003 by purpose of contract (choice of 4)

- Did contracting out in 2003 replace biotechnology employees in your firm? (yes/no), if yes, number of employees by type of position (choice of 7)
- Business practices: level of importance of each of the following reasons on your decision to contract out (choice of 7 reasons and 5 degrees)
- Does your firm provide contract services to other firms or organizations (yes/no); if yes, number of contracts entered into in 2003, revenues received and sources of the contract (choice of 5 sources)
- Was your firm involved in biotechnology-related cooperative/collaborative arrangements with other companies or organizations? (yes/no) if yes number of arrangements by partner type (choice of 4) and by arrangement purpose (choice of 8)
- Was your firm involved in biotechnology-related cooperative/collaborative arrangements with foreign companies or organizations? (yes/no) if yes, number of arrangements by partner type (choice of 5) and by geographic location (choice of 4), reasons by arrangement purpose (choice of 8 and 5 degrees for each purpose)
- Patents? (yes/no) if yes, the number, Existing and Pending by Patent office, number of unique patent applications your company submitted in 2002 and 2003
- Intellectual property: Did your firm grant biotechnology related intellectual property rights to another firm? (yes/no) if yes the number of IP rights by type of IP (choice of 4 IP instruments) and by country (choice of 3); Revenue from IP licensing in 2003
- Did your firm obtain biotechnology related intellectual property rights from another firm? (yes/no) if yes, the number by type of IP (choice of 4) and by country (choice of 3); Cost to your firm of obtaining IP in 2003
- Firm characteristics and financial profile: revenue, Research and Development expenditures and % of biotechnology R&D spending contracted out in 2002 in 2003 and forecast of 2005
- Attempt to raise capital (yes/no) if yes, what were the reasons (choice of 6), were you successful (yes/no) if yes, how much, was target reached (yes/no) if no, reasons given by lender (choice of 7), source of funding (choice of 10)
- Do you plan to raise capital in 2004 (yes/no) if yes how much (choice of 3)
- Apply for tax benefit in past 5 years (yes/no) if yes, how much did you apply for and how much did you receive, if no why not (choice of 4), have any of your SR&ED credits expired? (yes/no)
- Apply for provincial R&D tax benefit or incentive? (yes/no) if no, reasons (choice of 4)
- Exports of biotech products? (yes/no) if yes, value and percentage of exports, by geographic location (choice of 4) for 2002, 2003 and a 2005 forecast
- Imports of biotech products? (yes/no) if yes, value and percentage of imports, by geographic location (choice of 4) for 2002, 2003 and a 2005 forecast
- Bioproducts: Does your firm currently make or develop any bioproduct? (yes/no), if yes, number of bioproducts by category (choice of 8) and by stage of development (choice of 3)
- Current use of renewable or sustainable feedstock/materials? (yes/no), if yes, check the type (choice of 7)
- Financial profile: revenue (total and from bioproducts), exports from bioproducts, imports of bioproducts, R&D in 2002 in 2003 and forecast of 2005
- Human resources in bioproducts development: number of employees in Canada, number of employees with bioproducts-related activities, number of full-time employees with bioproductsrelated activities, number of part-time employees with bioproducts-related activities

- Strategies used in 2003 (12 choices of strategies and 5 degrees)
- Time to complete the questionnaire.

Reference Year: 2003.

Periodicity: Occasional.

Output: Survey was in the field in spring 2004. First results are expected in fall 2004.

Survey attached in annex

Collection/compilation agency: Canadian Department of Foreign Affairs and International Trade has documents on biotechnology in different counties: Australia, Japan (http://www.dfait-maeci.gc.ca/ni-ka/scitech/biotech-e.asp), Germany, Ireland, Korea, Mexico, the United Kingdom, the United States, etc.

Collection/compilation type: Market studies.

Variables:

- Number of employees
- Predicted employment in 2000
- Useful Internet sites.

Scope: National.

Frequency: N/A

Periodicity: N/A

Classification used: None.

Definition used: N/A

Output: Documents on biotechnology in different countries.

Contact comments: Market studies with some basic data and the evolution of biotechnology for the countries are generally available.

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: http://www.dfait-maeci.gc.ca/

1. CHINA

Collection/compilation agency: Shanghai Science and Technology Commission

Collection/compilation type: Biotechnology experimental survey in Shanghai.

Variables: The survey vehicle is in two parts: the first is three tables for quantitative indicators; the second is 8 groups of questions, most of which are non-quantitative.

In survey form:

- Basic statistical data of revenue, profit, employee number, R&D funding
- List of projects
- List of products

In survey questionnaire:

- Status of the associated biotechnological areas
- Application areas (scope) and products in biotechnologies
- Human resources
- Financial resources
- Intellectual properties
- Cooperation and exchanges
- Effect of biotechnological activities
- Development strategies for biotechnological activities.

Scope: Corporations in Shanghai, which are in accord with the statistical definition, include independent research organizations, universities and colleges and companies.

Frequency: Onetime survey carried out in 2004 for reference year 2003.

Periodicity: N/A

Classification used: Biotechnology classification (Shanghai, 2003).

1	Microorganism engineering
101	Microbial strains: screening, mutation, storage,
	purification, culture, and various analytical methods
	concerning varied targeted objects
102	Medium and sterilization
103	Fermentation
104	Parameter detection and analytical technologies
105	Isolation and purification of Bioproducts
106	Microbial products
107	Microbial technologies in polar boiling and special
	environment
108	Others

201 Production and preparation of enzyme preparations: fermentation, culture of animal and plant cells, extraction 202 Analysis of enzymatic activity 203 Enzyme reactors: immobilized enzymes, free enzymes 205 Bio-sensors 206 New enzyme preparations 207 Others 3 Cell engineering 301 Culture of plant cells (tube plants) 302 Culture of plant cells 303 Culture of animal cells 304 Animal tissue and organ engineering 305 Cell fusion: asymmetric fusion, cytoplasmic hybrid protoplast fusion 306 Monoclonal antibody 307 Stem cell 308 Chromosome engineering: polyploid, haploid, gynogenesis, andrigenesis 309 Embryo engineering: artificial insemination, embryonic transplantation, embryonic merogenesis and fusion, sex control, tube animals and infants, breezed embryos, breezed sperm 310 Cell recombination 311 Clone: embryonic cell clone, somatic clone, cloned organ, clonal human being 312 Cell bio-reactor 313 Transgenic choned animals 314 Transgenic choned animals 315 ot	2	Enzyma anginaaring
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	424	Functional Genomics
425 Structural genomics	425	Structural genomics

426	Transgenic food
427	Transgenic animals
428	Transgenic plants
429	Transgenic microbial
430	Others
5	Biochemical engineering
501	Automatic control
502	On-line parameter detection and analysis
503	Dynamics of bio-reactions
504	Bio-reactors
505	Amplified processes of bio-reactions
506	Biological products
507	Cytoclasis
508	Salting out
509	Extraction
510	Precipitation
511	Chromatography
512	Others
6	Protein Engineering
601	Expression system
602	Isolation and purification of proteins
603	Fusion protein
604	Protein folding
605	Protein modification
606	Gene modification
607	Structure prediction
608	Protein product
609	Others
7	Metabolism engineering
701	Metabolism regulation
702	Metabolism network
703	Induction and blockade
704	Flow of metabolites
705	Others
8	Miscellaneous (mainly including biomedicine
	engineering, biomaterials, etc.)
801	Enviromental-friendly bio-materials
802	Degradable biomaterials
803	Bio-medical materials
804	Bio-functional materials
805	Bio-thermodynamics
806	Biophysics
807	Others

Definition used: Biotechnology is an activity to modify living organisms or processing biological material according to beforehand design, which is based on modern life science, and combined with advanced engineering technology and other basic science theory, to provide products or services.

Output: Shanghai Biotechnology Survey Report in 2003, planned to be released in September 2004.

Contact comments: This was a regional experimental survey in Shanghai, China.

Future plans: Future plans will depend on the analysis of the results of the survey.

Contact details: www.stcsm.gov.cn

2. CHINA

This survey is in two parts

Collection/compilation agency: Ministry of Science and Technology

Collection/compilation type: Biotechnology Industry Park Survey.

Variables:

- General Information: Development plan, supported policy, problem and advice during Biotechnology Industry Park development
- Park information: Name, certified time, Type, planned area, exploited area, output value, pre-tax profit, Investment
- S&T activity: Number of S&T project, R&D expenditure, R&D expenditure as a percentage of total expenditure for the Park, R&D personnel, R&D personnel as a percentage of total employees for the Park, patents received and patents granted since the Park established
- Operating information: Company number in the Park, company employee, output value, pre-tax profit, investment by Source of Funds

Scope: National.

Frequency: 2003.

Periodicity: Onetime survey.

Definition: No definition is provided in the survey.

Output: Only available in Chinese and without publication.

Contact details: NA

Collection/compilation agency: Ministry of Science and Technology

Collection/compilation type: Biotechnology Company Survey.

Variables:

- Company information: Company name, founder background, type of registration, located park name, time of enter park, registered capital, fixed assets, output value per year, enterprise tax, total expenditure, type of major activity, type of major product
- Employees: Total, employee structure by work and by education level
- Patent: Useful time, country covered, application fee, holding fee, R&D expenditure

- Major product: Sales revenue, profits, technology level of product, technology level of productive equipment, resource of core technology, market shares in domestic and abroad, belonging to which national S&T program
- R&D activity: R&D personnel, intramural R&D expenditure, extramural R&D expenditure.

Scope: Companies in Biotechnology Industry Park

Frequency: 2003.

Periodicity: Onetime survey.

Definition: No definition is provided in the survey.

Output: Only available in Chinese and without publication.

Contact details: NA

CZECH REPUBLIC

Collection/compilation agency: Czech Statistical Office

Collection/compilation type: R&D Survey.

Variables: As of 2005, biotechnology R&D expenditure will be surveyed.

Scope: All sectors of performance.

Frequency: Annual.

Periodicity: There is a proposal to survey biotechnology R&D expenditures annually as of 2005.

Classification used: Sector of performance, by NACE.

Definition used: OECD definition of biotechnology.

Output: Publication on R&D Indicators.

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: http://www.czso.cz/

DENMARK

Collection/compilation agency: Danish Centre for Studies in Research and Research Policy

Collection/compilation type: R&D Survey, list of biotechnology firms.

Variables:

- R&D units
- R&D personnel
- Total employees
- R&D expenditure
- R&D cost, % R&D devoted to biotechnology.

Scope: Public (includes university R&D) and private sectors.

Frequency: Biennial as of 1991.

Periodicity: Annual.

Classification used: N/A

Definition used: No explicit definition is given in the national R&D questionnaire.

Output: N/A

Contact comments: Data available for: 1991-2001 (Though total number biotechnology firms: 1997-2003).

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: http://www.cfa.au.dk

Survey attached in annex

1. FINLAND

Collection/compilation agency: Statistics Finland

Collection/compilation type: Additional question in the 2003 R&D survey.

Variables:

- Biotechnology R&D: yes/no
- Biotechnology R&D expenditure (as percentage of total R&D).

Scope: Business enterprise sector, higher education sector, government sector.

Frequency: Onetime survey, continuation not known.

Periodicity: Yearly data for 2003.

Classification used: Institutional sector, industry (NACE), size of enterprise.

Definition used: OECD definition of biotechnology.

Output: Scheduled December 2004.

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: <u>http://www.tilastokeskus.fi/</u>

2. FINLAND

Collection/compilation agency: Academy of Finland

Collection/compilation type: Onetime background survey for the evaluation of the impact of public research funding on biotechnology and related life sciences in Finland. The purpose of the data collection was not to produce national statistics, but instead to provide the international panel with a clear picture of the Finnish innovation system in biotechnology and the roles and strategies of various actors.

Variables:

Organisation, strategy and resources:

- Mission, organisation and administration
- Organisation of basic biotechnology training, biotechnology research and researcher training at the university (question addressed to universities only)
- Research strategy / Biotechnology strategy / Biotechnology research in the strategy of the funding organisation
- Research funding for biotechnology in 1996–2001
- The use and impact of earmarked biotechnology funding from the Ministry of Education
- Research personnel in 1996 and 2001
- Core facilities.

Additional questions for ministries:

- Biotechnology research (*e.g.* the sector's role in the biotechnology innovation system)
- Management by results.

Additional questions for funding organisations:

- Funding organisation and the biotechnology innovation system
- Biotechnology R&D funding in 1996–2001 by funding mode/category
- Biotechnology R&D funding in 1996–2001 by receiving organisation
- Development of biotechnology R&D funding before 1996.

Research and its impact:

- Major projects (interventions in the case of funding organisations) in the field of biotechnology and its applications in 1996–2001
- Scientific impact in terms of biotechnology publications in 1996–2001
- Research collaboration in terms of joint publications in 1996–2001
- Research collaboration in terms of EU projects in 1996–2001
- Researcher training in terms of doctoral degrees in 1996–2001

- Mobility of researchers (question addressed to biocentres only)
- Technology transfer
- Socio-economic impact in terms of patents, licensing and spin-off companies
- Other socio-economic impacts
- The biocentre as part of the local innovation system (question addressed to biocentres only).

SWOT analysis (strengths, weaknesses, opportunities, threats) and future visions:

- Self-evaluation using the method of SWOT analysis
- Visions of biotechnology-related activities by 2007
- The future of biotechnology funding.

Scope: Biocentres within universities, universities and research institutes conducting research in the field of biotechnology, ministries concerned, and public funding organisations. The questionnaire was tailored to each group of respondents.

Frequency: N/A

Periodicity: Onetime survey in 2002.

Classification used: N/A

Definition used: In the evaluation, *biotechnology is understood to cover all life sciences research that uses the methods of modern biology and the applications of this research.* OECD definition of biotechnology, this definition is supposed to help the respondents decide whether a certain kind of research activity can be classified as biotechnology.

Output: Biotechnology in Finland. Impact of Public Research Funding and Strategies for the Future. *Evaluation Report.* Publications of the Academy of Finland 11/2002.

An example of the survey questionnaire was published as 'Appendix VIII E' in the evaluation report. The report is available on the Academy of Finland Web site (<u>http://www.aka.fi/eng</u> -> Publications -> Publications series).

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: http://www.aka.fi/eng

The survey is available in the publication at: An example of the survey questionnaire was published as 'Appendix VIII E' in *Biotechnology in Finland. Impact of Public Research Funding and Strategies for the Future. Evaluation Report.* The report is available on the Academy of Finland Web site: (<u>http://www.aka.fi/eng</u> -> Publications -> Publications series).

1. FRANCE

Collection/compilation agency: MENRT (Ministère de l'éducation nationale, de la recherche et de la technologie – Bureau des études statistiques sur la recherche) and INRA/SERD (Institut National de la Recherche Agronomique)

Collection/compilation type: A biotechnology firm survey was developed in collaboration with INRA (Institut National de la Recherche Agronomique). Prior to this survey MENRT commissioned a study by Arthur Andersen to set up a register of enterprises.

Variables:

- Name of the firm and key top executives
- Main technologies developed and implemented by the company (list of 33 technologies)
- Main areas of business (markets) in which the company operates (list of 28 markets)
- Revenues, R&D expenditure, net earnings and work force over the last three years
- Patents used and owned by the company
- Quality certification
- Actual and targeted partnerships in fields of research, production and marketing.

Scope: Public academic laboratories and private enterprises.

Frequency: Annual.

Periodicity: Annual.

Classification used: See Definition used.

Definition used: Rather than defining biotechnology France has established a list of 35 biotechnologies (available in French only at present):

Amplification de gènes – PCR	Enzymologie	Modélisation moléculaire
ADN recombinant	Fermentation	Molécules antisens
Anticorps monoclonaux	Fonctionnalisation des genes	Pharmacogénomique
Bioinformatique	Galénique	Protéomique
Bioprocess	Hormones et facteurs de croissance	Purification/séparation
Biopuces	Hybridation, fusion cellulaire	Séquençage
Bio-réacteur	Ingéniérie des glucides	Synthèse des molécules
Chimie chorale	Ingéniérie des lipides	Système de délivrance (vecteurs)
Chimie combinatoire	Ingéniérie des proteines	Traitements des produits et substituts sanguins
Contrôle des procédés	Ingéniérie des tissues	Transgénèse
Criblage de molécules haut débit	Instrumentation	Autres : préciser :
Culture des tissus ou des cellules	Isolation de peptides et synthèse	

Output:

Biofutur, Bio-industry: the European Dream, (February 2000)

INRA, Is The Creation And Development Of Biotechnology SMEs Localised?, by S. Lemarié, V. Magematin, A. Torre (2000)

INRA, *Strategies Of European SMEs In Biotechnology: The Role Of Size, Technology And Market?*, by S. Lemarié, M.-A. de Looze, V. Mangematin (2000)

Contact comments: France counts approximately 1 000 biotechnology units of which approximately 700 are public academic laboratories and the remainder private enterprises. The survey was sent out to these labs and enterprises.

Of all the companies to which the questionnaire was sent, less than 450 corresponded to the final criteria. It can therefore be considered that the sample analysed corresponds to around half of the biotechnology firms operating in France. The analysis was based on 194 firms, for which all the requested information was available.

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: http://biotech.education.fr/apropos.asp

2. FRANCE

Collection/compilation agency: MENRT (Ministère de l'éducation nationale, de la recherche et de la technologie – Bureau des études statistiques sur la recherche)

Collection/compilation type: A biotechnology firm survey was developed along the OECD recommendations.

Variables:

- Name of the firm
- Address
- NACE code
- Activity portfolio
- R&D work force in 2001
- External R&D, R&D execution for an other company, for itself
- Public human and material supports
- The technological level of firms against national and international competitors.

Scope: Private enterprises.

Frequency: Annual.

Periodicity: Onetime study for 2001.

Classification used: N/A

Definition used: OECD definition of biotechnology. The following is the French translation: La biotechnologie est définie par l'utilisation de techniques impliquant du matériel vivant : servant à modifier des organismes vivants existants ou des parties de ceux-ci ou ; servant à transformer du matériel, d'origine vivante ou non, par l'utilisation de procédés impliquant des organismes vivants et ayant pour objectif de produire de nouvelles connaissances (scientifiques) ou de développer de nouveaux produits ou procédés.

Output: Les entreprises de biotechnologies en France en 2001: <u>http://cisad.adc.education.fr/reperes/telechar/nr/nr0301.pdf</u>

Contact comments: By exploiting the responses to the mandatory annual R&D survey the survey has identified 650 biotechnology firms. Through the unique identification number of the firm, the biotechnology firms can be cross-referenced against all the available national surveys and data sets (CIS3, Patent, fiscal files etc.). Usual variables such as age, turnover can be determined upon request.

Future plans (plans for new collections, strategies, experiences etc.): $N\!/\!A$

Contact details: http://cisad.adc.education.fr/reperes/default.htm

Survey attached in annex

3. FRANCE

Collection/compilation agency: MENRT (Ministère de l'éducation nationale, de la recherche et de la technologie – Bureau des études statistiques sur la recherche)

Collection/compilation type: R&D Survey was developed along the OECD recommendations.

Variable:

• The percentage of internal R&D annual expenditures dedicated to biotechnology.

Scope: Private enterprises.

Frequency: Since 2000.

Periodicity: Annual.

Classification used: N/A

Definition used: OECD definition of biotechnology. The following is the French translation: « Les biotechnologies : on rappelle la définition de l'OCDE : « application des principes de la science et de l'ingénierie au traitement de matières par des agents biologiques dans la production de biens et de services ».

Quelques exemples (non exhaustifs) de biotechnologies : ADN recombinant, amplification de l'ADN, thérapie génique, anticorps monoclonaux, génie génétique, séquençage, biovalorisation, bioinformatique, enzymologie, fermentation, ... ».

Output:

Recherche et développement en France - Résultats 2000, estimations 2001, 2003 <u>http://cisad.adc.education.fr/reperes/telechar/res/res00/dossier00.pdf</u>

Contact comments: Pharmaceutical firms tend to put 100% of their activities in biotechnology since biotechnology is the closest R&D branch that is proposed (see below). 401 firms gave a positive answer for 2001.

Future plans (plans for new collections, strategies, experiences etc.):

- To continue collecting data
- To check and improve the quality of responses.

Contact details: http://cisad.adc.education.fr/reperes/default.htm

Survey attached in annex

1. GERMANY

Collection/compilation agency: Statistisches Bundesamt (Federal Statistical Office Germany)

Collection/compilation type: Special onetime voluntary surveys were conducted in 1992: by the Stifterverband for the Business enterprise sector and by the Federal Statistical Office for the higher education sector. A mandatory survey covered the government research institutes and the private non-profit organisations.

Variables: For the Business enterprise sector: Intramural expenditures by type of research activity

- Intramural expenditures by economic branches (industry)
- Intramural expenditures by product group
- Extramural expenditures by business enterprises for biotechnological research.

For the higher education sector:

- Proportion of total working time of academic personnel attributable to biotechnological research
- Expenditures by institutes of higher education for biotechnological research
- Expenditures by funding category
- Expenditures by fields of sciences
- Institutions of higher education involved in biotechnological R&D.

For the government research institutions and private non-profit organisations:

• Expenditures for biotechnological research by government research institutions and private non-profit organisations.

Scope: Business enterprise sector, Higher Education sector, government research institutions and private non-profit organisations.

Frequency: Onetime study for 1992.

Periodicity: Annual.

Classification used: See variables.

Definition used: "Biotechnological R&D is defined for the purposes of the survey as a systematic, creative work integrating biology, micro-biology, molecular biology and engineering sciences in order to utilise or to increase the potential of living organisms or their cellular or sub-cellular or molecular components for the development of products, processes and services. R&D in biotechnology was further subdivided into R&D in biotechnology (excluding genetic engineering) and R&D in genetic engineering."

Output: Statistisches Bundesamt, Ausgaben für biotechnologische Forschung (1995)

Contact comments: This study presents the results of the 1992 study the Federal Ministry of Education Science, Research and Technology commissioned the Federal Statistical Office to undertake in order to assess biotechnological R&D expenditures in Germany.

Contact details: <u>http://www.statistik-bund.de</u>

2. GERMANY

Collection/compilation agency: Federal Statistical Office - Germany

Collection/compilation type: Biotechnology firm survey.

Variables:

- Number of enterprises
- Regional distribution of enterprises
- Total employees
- R&D employees (biotech)
- R&D expenses; turnover/sales
- Venture capital shareholding of financial service providers.

Scope: The target population was sub-divided into five categories of enterprises that make up the German biotechnology landscape:

- Category I: Biotechnology core enterprises applying mainly modern biotechnological procedures
- Category II: Suppliers to the biotechnology core enterprises and research institutions
- Category III: Enterprises working both as biotechnology core firms and suppliers
- Category IV: Large life sciences industry enterprises with a significant focus on biotechnological activities
- Category V: Consultants and financial service providers in the biotechnology branch.

Frequency: Biennial.

Periodicity: 2000 and 2002.

Classification used: See scope.

Definition used: OECD definition of biotechnology.

Output: Federal Statistical Office, Unternehmen der Biotechnologie in Deutschland – Ergebnisse einer Pilotstudie für das Jahr 2000 (<u>http://www.destatis.de/presse/deutsch/pk/2002/biotechnologie_2000.pdf</u>)

Unternehmen der Biotechnologie in Deutschland – Ergebnisse der Wiederholungsbefragung 2002 (http://www.destatis.de/presse/deutsch/pk/2003/biotechnologie_2002i.pdf)

Contact comments: Both surveys were done on a voluntary basis. The response rate was, per category (see scope), between 40 and 65% (overall it was approximately 58%).

Future plans (plans for new collections, strategies, experiences etc.): The next survey is planned for 2004 (reference year).

Contact details: http://www.destatis.de/

The survey is available in the publication at: http://www.destatis.de/presse/deutsch/pk/2003/biotechnologie_2002i.pdf

GREECE

Collection/compilation agency: General Secretariat for Research and Technology, S&T Indicators Division

Collection/compilation type: Biotechnology data are collected only through the ordinary procedures used to measure the government financing of R&D (Government Budget Appropriations or Outlays for R&D by socio-economic objectives).

Basically two distinct procedures are used in a complementary way:

- Text analysis (based on various types of data kept by government agencies which fund or administer R&D activities); and
- Carrying out of a specific Government Budget Appropriations or Outlays for R&D (GBAORD) survey (addressed to government R&D performing institutions and PNP institutions).

Data collected in this way refer to the government financing on biotechnology R&D and not to the amount of money finally spent on biotechnology by the R&D performers.

Variables: Government spending on biotechnology R&D by socio-economic objectives.

Scope: The aim is to identify all government spending on biotechnology R&D for a specific reference year. However the absence of respective data for NABS objective 10 (which includes R&D in the higher education sector financed from general purpose grants from ministries of education (General University Funds)), due to special methodological aspects of the estimation of these funds, leads to serious underestimation of the importance of biotechnology in the overall government financing of R&D.

Frequency: Annual (Latest available year: 2002 (Provisional data)).

Periodicity: Annual.

Classification used: The classification of the objectives used is the "Nomenclature for the analysis and comparison of scientific programmes and budgets" (NABS) at sub-chapter level.

Definition used: The definition used in the survey questionnaire refers to "all activities aiming at the production of theoretical knowledge and know-how about the impact of biological factors on different materials for the production of goods or services."

Output: Reports on Government Budget Appropriations or Outlays for R&D.

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: <u>http://www.gsrt.gr</u>

1. HUNGARY

Collection/compilation agency: Hungarian Central Statistical Office

Contact comments: As of 2005 questions related to biotechnology will be inserted into the Hungarian annual R&D survey.

Contact details: http://www.ksh.hu/

2. HUNGARY

Collection/compilation agency: IKU (Innovation Research Centre) and FhGISI (Fraunhofer Institute for Systems and Innovation Research)

Collection/compilation type: Audit.

Variables:

- Number of firms by size class: turnover (total and just bio)
- Using turnover size categories: export earnings (total and just bio)
- export to advanced countries
- R&D expenditure
- Number of firms by size class
- Employment (total and just bio)
- Using employees size categories: R&D staff (total and just bio)
- Scientific staff
- Technical staff.

And institutes:

- Firms and institutes ranking: own contribution to biotechnological methods
- Impeding factors to R&D in biotechnology
- Existing and expected capabilities
- Objectives for innovation in 1996
- Domestic patent holders (at the beginning of 1996)
- Importance of partners
- Importance of external co-operation in R&D
- Self-evaluation of in-house factors
- Evaluation of external factors of competitiveness
- R&D resources in comparison to main competitors
- R&D output in comparison to main competitors
- Number of biotechnology-related contracts in OMFB bidding system, by sector (1991-96, January)
- Number of patent applications in Hungary
- First 30 filers of recombinant biotechnology in Hungary.

Scope: Business enterprise, higher education, private-non-profit and government sectors.

Frequency: Onetime 1996.

Periodicity: N/A

Classification used: N/A

Definition used: "For this project a rather broad understanding of biotechnology is used defining biotechnology as any technique that uses living organisms or parts thereof to make or modify products, to degrade substances to modify living organisms (plants, animals, micro-organisms) for specific uses, or for services (*e.g.* in analytical laboratories). Following this definition genetic engineering is not synonymous with biotechnology but rather one of the several methods which are used in biotechnology."

Output: Bio-Technology Audit in Hungary, Guidelines, Implementation, Results Ulrike Bross, Annamária Inzelt, Thomas Reiss.

Contact comments: N/A

Contact details: IKU Innovation Research Centre Postal address: Hungary-1428 Pf.12.

ICELAND

Collection/compilation agency: The Icelandic Research Centre - RANNIS

Collection/compilation type: R&D Survey for 1999 and a Dedicated Biotechnology Use and Development survey for the 2001 to 2003 period.

Variables: Information about statistical unit:

- Turnover of R&D performing organisations
- R&D expenditures on biotechnology and financing of those expenditures
- Personnel in full-time equivalent and headcount with gender classification
- Co-operation with others in field of biotechnology R&D (subdivided into six categories)
- Objectives of the biotechnology R&D activities (subdivided into nine activities)
- Main results of biotechnology R&D
- Number of patents grants and applications
- Number of publications from biotechnology R&D
- Number of spin-offs
- Fields of science in new projects related to R&D in biotechnology
- Obstacles met regarding R&D in biotech
- Main success of R&D in biotech.

Scope: All sectors involved; business enterprise, private non-profit, higher education and public research institutes.

Frequency: Two *ad hoc* surveys were carried out. Questions were included in the 1999 in the R&D survey for the first time. A dedicated biotechnology use and development survey was carried out for the 2001 to 2003 period.

Periodicity: Ad hoc.

Classification used:

For R&D work on biotechnology:

uman health:
Diagnostics (e.g. immunodiagnostics, gene probes, biosensors)
Therapeutics (<i>e.g.</i> vaccines, immune stimulants, Biopharmaceuticals, rational drug design, drug delivery mbinatorial chemistry)
Genomics and Molecular Modelling (<i>e.g.</i> DNA/RNA/protein sequencing & databases for humans, plants, imals and microorganisms)
griculture:
Plant Biotechnology (e.g. tissue culture, embryogenesis, genetic markers, genetic engineering)
Animal Biotechnology (<i>e.g.</i> diagnostics, therapeutics, embryo transplantation, genetic markers, genetic gineering
Biofertilizers/Biopesticides/Bioherbicides/Biological Feed Additives/Microbial pest control (<i>e.g.</i> bacteria, ngi, yeasts)
Fish health (<i>e.g.</i> diagnostics, therapeutics)
Broodstock genetics (e.g. Tracking superior traits, genetic modification/ engineering)
Bioextraction (<i>e.g.</i> karageenan from seaweed, antifreeze proteins from fish, flavours) Silviculture (<i>e.g.</i> ectomycorrhizae, tissue culture, somatic embryogenesis, genetic markers, genetic igineering)
dustry:
Bioprocessing (e.g. using enzymes and bacteria culture)
Prunctional Foods/Nutriceuticals (e.g. probiotics, unsaturated fatty acids)
nvironment
Environment
her
Other fields of biotechnology, which

Agriculture
Fisheries
Aquaculture
Fish processing
Food processing
General industry
Environm. prot. pollution.
Health care
Others what

Definition used: OECD definition of biotechnology.

Output: The OECD published a RANNIS paper presenting the 1999 survey. A publication covering the 2001 to 2003 period is forthcoming.

Future plans (plans for new collections, strategies, experiences etc.): No plans have been made yet for continuing the study on R&D in biotechnology. It is however rather clear that the newly established Science and Technology Policy Council and its committees, together with the Ministries involved, have shown great interest in being updated on the subject. It should be noted that it was the Ministry of Education, Science and Culture that requested RANNIS to carry out the survey for the 2001 to 2003 period.

Contact comments: N/A

Contact details: http://www.rannis.is/

Survey attached in annex

1. INDIA

Collection/compilation agency: Department of Biotechnology, Government of India

Collection/compilation type: Annual Budget Papers of the Department

Variables: Budgetary allocations to Department of Biotechnology.

Scope: Government sector, public institutes.

Frequency: Annual.

Periodicity: Annual.

Classification used: Field of Research.

Definition used: No definition is used.

Output: Annual Report 2003-04, Department of Biotechnology, Government of India.

Contact comments: Not all the heads of budgetary expenditure clearly identify the nature of biotechnology thus leading to overlapping of data.

Future plans (plans for new collections, strategies, experiences,etc.): Government is considering the proposal to launch a detailed survey based on the work programme at the Asian Cooperation Dialogue (ACD).

Contact details: http://www.dbtindia.nic.in/aboutdbt/overviewmain.html

2. INDIA

Collection/compilation agency: Biotechnology Consortium India Limited (BCIL)

Collection/compilation type: Directory.

Variables:

- Name of establishment
- Address
- Biotechnology Sector
- Foreign Alliance
- R&D Expenditure
- Patents.

Scope: Firms engaged in biotechnology R&D, services and production.

Frequency: Occasional (1992, 1995, 2001, 2003).

Periodicity: N/A

Classification used: Every industrial unit and institute is classified into the following categories:

- Agriculture
- Bioinformatics
- Biotechnology Park
- Contact Services
- Environment
- Equipment
- Health Care
- Industrial Biotechnology

Definition used: N/A

Output: Directory of Biotechnology Industries and Institutions in India 4th Edition, BCIL, New Delhi.

Contact comments: Since the definition used is not clear it becomes likely that the data may be double counted and firms active in more than one sector may be missing.

Future plans (plans for new collections, strategies, experiences etc): N/A

Contact details: http://www.biotech.co.in

3. INDIA

Collection/compilation agency: Patent Facilitating Centre, Technology Information, Forecasting and Assessment Council (TIFAC)

Collection/compilation type: Patent applications.

Variables: Patent applications.

Scope: All Sectors

Frequency: N/A

Periodicity: N/A

Classification used: N/A

Definition used: No definition is used.

Output: News letters and sector-specific reports.

Contact comments: PFC is a recently established entity which has taken up the work on patents applied in different areas. Biotechnology is one of the areas in which they are planning to initiate a work programme. Recently PFC finished a study on micro-organisms.

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: <u>http://www.tifac.org.in/</u>

IRELAND

Collection/compilation agency: Forfás

Collection/compilation type: R&D Survey.

Variables: Percentage of R&D attributable to biotechnology.

Scope: Private sector enterprises and commercial state-sponsored organisations with a production or service function are covered in the business survey.

Frequency: First time in survey for reference year 2001.

Periodicity: Biennial.

Classification used: N/A

Definition used: No definition used in 2001 R&D survey, however the OECD definition of biotechnology will be used as of 2003.

Output: Business Expenditure on Research and Development (BERD), 2001, 2003.

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: http://www.forfas.ie/

ISRAEL

Collection/compilation agency: Israel Central Bureau of Statistics (CBS)

Collection/compilation type: Survey of Biotechnology in Israel for 2002.

Variables:

- Biotechnologies and their uses
- Fields of biotechnological activities
- Sources of knowledge
- Sources of Funds
- Patents
- Sales (exports and local market)
- Income, investments
- R&D expenditures
- Employees composition and quality and their labour cost.

Scope: R&D and innovate production companies engaging in biotechnology.

Frequency: N/A

Periodicity: N/A

Classification used: According to biotechnological activities.

Definition used: OECD definition of biotechnology.

Output: Preliminary findings.

Contact comments: Final Findings will be published closer to the end of 2004.

Future plans (plans for new collections, strategies, experiences etc.): 1) Possibility for a new biotechnological companies survey. 2) Biotechnological activities in R&D, deriving from the annual R&D Survey in Business Sector.

Contact details: http://www.cbs.gov.il

Survey attached in annex

ITALY

Collection/compilation agency: National Institute of Statistics (ISTAT)

Collection/compilation type: R&D Survey.

Variables: R&D expenditure (percentage by type of activity listed in the OECD list_based definition)

Scope: Business enterprise.

Frequency: Annual (data on biotechnologies are available since 1991).

Periodicity: Annual.

Classification used: Since 2002 (with reference to the Italian 2001 R&D survey) ISTAT has adopted a definition of biotechnologies for statistical use resulting from the combination of both the "single definition" and the "list_based definition" as proposed by the OECD *ad hoc* group.

Definition used: OECD definition of biotechnology.

The Italian version, jointly developed by ISTAT and the Italian Delegation to the OECD Working Group on Biotechnology, is as follows:

"L'applicazione di scienza e tecnologia agli organismi viventi (per esempio, microrganismi, piante, animali) e loro parti o prodotti, realizzata al fine di ottenere conoscenze, beni e servizi mediante la modificazione di materiali biologici (viventi o non viventi)".

Output: Data on the percentage of R&D activities related to biotechnologies will be published for the first time in 2004 (2001 data).

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: <u>http://www.istat.it/</u>

1. JAPAN

Collection/compilation agency: Statistics Bureau, Ministry of Public Management, Home Affairs, Posts and Telecommunications, Japan (formerly known as the: Statistics Bureau, Management and Coordination Agency of the Government of Japan)

Collection/compilation type: R&D Survey on Life Sciences.

Variables:

- Number of persons engaged in gene recombination (rDNA) R&D
- R&D Expenditures.

Scope: Companies, research institutes, universities and colleges.

Frequency: Annual. Questions were incorporated in 1995/1996. The last time these questions were included was for 1997/1998.

Periodicity: Annual.

Classification used: N/A

Definition used: Gene recombination research and development (recombinant DNA research and development) means research and development relating to creation of cells having new genetic traits by recombining with a gene of a different species after cutting and joining genes from certain organisms (DNA, deoxyribonucleic acid, chemical substance of a gene), using enzyme, and then transplanting it into a cell of a different species of organism. The results can be applied to basic research and development and medicine, agriculture, industry, and energy and environmental protection.

Output: *Report on the Survey of Research and Development*, Annual.

Contact comments: N/A

Contact details: http://www.stat.go.jp/english/index.htm

2. JAPAN

Collection/compilation agency: Japan Bioindustry Association (JBA)

Collection/compilation type: Biotechnology Industry Survey

Variables:

- Number of companies
- Company profile
 - Capitals, year established
 - o Employees
 - o Industrial fields.
- Product profile:
 - Product fields
 - o Technologies used
 - o Annual sales
 - o Estimated sales after 5 years.

Scope: Business enterprise.

Frequency: Annual as of 1997.

Periodicity: Annual.

Classification used: "Biotechnology" in this survey is the technology that utilises or imitates the function of living organisms to transform substances; exchange, treat, and transmit biological information; or exchange energy. Those technologies are utilised and practically applied in the following fields:

- 1. Biochemical processes: useful substance production, energy generation, environmental remediation, etc.
- 2. Creation of substances, materials, enzymes, microbes, and plant and animal with superior new functions.
- 3. Use of biological mechanism: genetic therapy, diagnostic technology, artificial organs, etc.
- 4. Highly sensitive and specific detection, measurement, and information transmission technologies utilising or imitating biological functions: biosensors, biocomputers, etc.
- 5. Technology to evaluate and analyse useful substances: evaluation of biologically active substances such as pharmaceuticals;
- 6. Research to elucidate biological mechanism.

The biotechnology targeted in this survey includes not only new biotechnology such as recombinant DNA technology, cell fusion, and cultivation of plant and animal cells, but also the conventional technology used in fermentation and brewing, cultivation, and mutagenesis.

"Biotechnology related products" in this survey are as follows.

- 1. Products produced at your firm, using processes employing biotechnology.
- 2. Products that although not produced using processes employing biotechnology in your firm, use materials that have been manufactured through biotechnology.
- 3. Products that although not produced using processes employing biotechnology in your firm, are using biotechnology as the main technology in the research and development stages.
- 4. Products whose materials purchased were produced using biotechnology such as described in (1)-(3), excluding those exported from foreign countries.
- 5. Instruments, machinery, facilities, and plants involved in production processes using biotechnology or biotechnology related research and development.
- 6. Services related to biotechnology such as analyses, tests, software, etc.

Output: Annual report, *Fundamental Survey on Creation of Biotechnology Industry*, (Japanese version only).

Contact comments: As of 2000, the JBA survey on the biotechnology industry is conducted under contract by the Ministry of Economy, Trade and Industry (METI).

Contact details: <u>http://www.jba.or.jp</u>

Survey attached in annex

1. KOREA

Collection/compilation agencies: Bio-Industry Association of Korea (BAK), Korea Institute for Industrial Economics & Trade KIET), Ministry of Commerce, Industry and Energy (MOCIE) and Korea National Statistical Office NSO)

Collection/compilation type: Bio-Industry Statistics Survey.

Variables:

- Company information: employees, sales, exports, imports
- Human resources in biotechnology activities
- Investment in biotechnology R&D and equipment
- Biotechnologies used.

Scope: Industry.

Frequency: Annual. Data are available from 1992 onwards. Korea's statistics on its bio-industry have been published by the Bio-Industrial Association of Korea (BAK) since 1992. From the 2002 statistical survey on the status of Korea's bio-industry, the biotechnology classification system was laid out to clarify the technical definition of bio-industry in co-operation with the Korea Institute for Industrial Economics & Trade (KIET), Ministry of Commerce, Industry and Energy (MOCIE) and the Korea National Statistical Office (NSO).

Periodicity: Annual.

Classifications used: Korea's Biotechnology and Bio-Industry Classification Systems.

Definition used: Bio-industry is defined as "products and processes produced with biotechnology" and the technologies currently used in the domestic bio-industry are grouped according to the biotechnology classification system.

Output: The Status of Korean Bio-Industry by BAK (since 1992, in Korean), The Survey Results of Korea's Bio-industry – 2002 by KIET, BAK, MOCIE and NSO.

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details:

http://www.bak.or.kr http://kiet.re.kr http://www.nso.go.kr

2. KOREA

Collection/compilation agency: Korea Institute of S&T Evaluation and Planning (KISTEP)

Collection/compilation type: Government R&D Survey

Variables: Budget of central governmental R&D expenditure:

- Percentage of R&D expenditure related to biotechnologies
- Scope: Government sector.

Frequency: Annual. Data are available from 2001 onwards.

Periodicity: Annual.

Classification used: N/A

Definition used: None.

Output: Governmental R&D investment for high technology (in Korean).

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: http://www.kistep.re.kr

LUXEMBOURG

No information is available at this time.

MEXICO

No information is available at this time.

NETHERLANDS

Collection/compilation agency: Central Bureau of Statistics (CBS)

Collection/compilation type: R&D Survey (until 2001).

Variables: R&D personnel (full-time-equivalents).

Scope: Business enterprise and government research institutes.

Frequency: Biennial.

Periodicity: Annual.

Classification used: Industry (2-digit NACE).

Definition used: Based on allocating R&D full time equivalents to 'field of technology' developed by CBS: Research on genetic modification, cell fusion/biology, fermentation, development of proteins/enzymes, neuro biology, botanical improvement, bio catalyse.

Output: Statline on the Web site (see below); Kennis en economie, publication (in Dutch).

Contact comments: From reference period 2003 onwards, the question on allocating R&D full-time equivalents to 'fields of technology' is skipped from the R&D questionnaire.

Future plans (plans for new collections, strategies, experiences etc.): No specific plans on collecting R&D figures on biotechnology.

Contact details: http://www.cbs.nl/

NEW ZEALAND

Collection/compilation agency: Ministry of Research, Science and Technology (MORST) and Statistics New Zealand (SNZ)

Collection/compilation type: Biotechnology firm survey.

Variables:

- Biotechnology processes used by business
- Stage of development of biotechnology processes
- Number of biotechnology processes used by the enterprise
- Type of biotechnology process used by the enterprise
- Industry sectors
- Percentage of sales represented by each industry sector
- Most important bioindustry sector
- Number of bioindustry sectors implemented in the last three years
- Number of bioindustry sectors planned to be implemented in the next three years
- Industry sectors that are expected to grow in the future
- New Zealand organisations on whose behalf research was carried out
- Overseas organisations on whose behalf research was carried out
- Strategic alliances New Zealand organisations
- Strategic alliances Foreign organisations
- Product and process sales
- Contract research revenue
- Royalty income
- Income from direct government subsidies and cash grants
- All other income
- Total income
- Raw materials and finished good opening stocks
- Raw materials and finished good closing stocks
- Research and development expenses
- Royalty payments
- Salaries and wages
- All other expenses
- Cost of raw materials sourced from New Zealand

- Cost of raw materials sourced from overseas
- Total expenses
- Total exports
- Total value of biotechnology exports
- Biotechnology exports to Australia
- Biotechnology exports to Asia
- Biotechnology exports to Europe
- Biotechnology exports to United States
- Biotechnology exports to other countries
- Number of projects abandoned due to inability to purchase IP rights
- Number of projects abandoned due to inability to licence IP rights
- Number of projects abandoned due to other reason
- Number of projects abandoned due to inability to access basic research
- Number of litigations
- Number of disputes
- Number of arrangements to share IP instruments
- Number of arrangements to share acquire IP instruments
- Number of successful biotechnology-related patent applications in the year ended 30 June 1999
- Number of successful biotechnology-related patent applications in the last five years
- Number of biotechnology-related articles published in refereed journals in the year ended 30 June 1999
- Number of conferences on biotechnology related subjects attended in the year ended 30 June 1999
- Total number of FTEs
- Number of FTEs involved in R&D
- Number of FTEs involved in quality assurance
- Number of FTEs involved in regulatory/legal/government affairs
- Number of FTEs involved in marketing and sales
- Number of FTEs involved in business development/finance
- Number of FTEs involved in administration/human resources
- Head count of those involved in R&D
- Head count of those involved in quality assurance
- Head count of those involved in regulatory/legal/government affairs
- Head count of those involved in marketing and sales
- Head count of those involved in business development/finance
- Head count of those involved in administration/human resources

- Head count by qualification
- Number of enterprises who have recruited staff from overseas
- Problems for biotechnology commercialisation
- Countries from which employees were recruited
- Reasons why foreigners declined an offer of employment.

Scope: Firms, government and university units engaged in modern biotechnology activities. The survey excludes all industries which use traditional forms of biotechnologies such as bread-, wine-, beer-making.

Frequency: First survey was carried out in 2000 for reference year 1998/99. Statistics New Zealand is currently in the process of running a Biotechnology Survey for the reference year 2003/2004 (post out in late August 2004), which will essentially be a repeat of a biotechnology survey last run in 1999.

Periodicity: Annual.

Classification used:

Industry:

• Australian and New Zealand Standard Industrial Classification (ANZSIC four-digit level).

Sector:

• New Zealand Institutional Sector Classification (NZISC).

Definition used: The 2000 survey carried the following definition: Modern biotechnology is defined as: The application of scientific and engineering principles to the processing of material by biological agents and the processing of biological materials to improve the quality of life by isolating, modifying and synthesising the genetic instructions responsible for actual biological processes.

The 2004 survey uses the OECD definition of biotechnology.

Output:

- Standard tables, approximately 30 standard tables would be produced.
- Biotechnological statistics would also be released in Key Statistics, the Yearbook and various other publications produced by SNZ.
- Statistics New Zealand (2001), Modern Biotechnology Activity in New Zealand, April.
- Results of the 2004 survey are scheduled for first release in April 2005.

Contact comments: In October 2003 Statistics New Zealand established a new work area (Business Performance Division) which is charged with producing statistics on the broad area of business performance, and in particular on areas such as:

- Research and Development
- Innovation
- Biotechnology
- Information and Communication Technology.

Future plans (plans for new collections, strategies, experiences etc.): A more comprehensive redevelopment, planned for the 2005/06 year, will incorporate work currently being undertaken by New Zealand Trade and Enterprises (NZTE) in developing a measurement framework for the Biotechnology sector.

Contact details: www.stats.govt.nz

Survey attached in annex

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NORWAY

Collection/compilation agency: Statistics Norway (SSB) and Norwegian Institute for Studies in Research and Higher Education (NIFU)

Collection/compilation type: R&D Survey.

Variables: Current R&D expenditures.

Scope: Statistics Norway (SSB) collects data for the private firms in the business enterprise sector. The Norwegian Institute for Studies in Research and Higher Education (NIFU) collects data for the non-profit institutes in the business enterprise sector, the higher education sector and the government sector (including the very small private non-profit sector in Norway).

Frequency: Biennial, the first time in 1985.

Periodicity: Annual.

Classification used: N/A

Definition used: Before 2003 the following definition was used: Biotechnology is the use of microorganisms, plants and animal cells for making or modification of products, plants and animals or the development of microorganisms for specific use. Biotechnology concerning "aquaculture" (from 2001 "marine R&D") is included in aquaculture.

From 2003 the OECD definition of biotechnology is used.

Output: The data are not published on a regular basis; however, some of these data have been used in newsletters/booklets.

Contact comments: The wording of the definition has changed several times. In 1985, the definition included aquaculture. In 1987, this area was separated from biotechnology. From 1991 onwards, biotechnology related to aquaculture was excluded from the biotechnology category. In the latest R&D surveys (1997, 1999 and 2001), the above-mentioned definition was used. From 2003 the OECD definition of biotechnology (single and list-based) is used.

Future plans (plans for new collections, strategies, experiences etc.): In 2003 a special questionnaire on biotechnology R&D was included with the regular R&D survey in the higher education sector; the government sector (including the very small PNP-sector in Norway) and the non-profit institutes in the business enterprise sector. Please note that this special questionnaire on biotechnology R&D was not sent to the business enterprise sector. The R&D survey for the business enterprise sector however has a question on the percentage of R&D expenditure attributable to biotechnology. The biotechnology survey is partially based on the results from the R&D surveys and will be published in early 2005.

Contact details:

http://www.nifu.no http://www.ssb.no

The special survey is attached in the annex.

POLAND

Collection/compilation agency: Ministry of Scientific Research and Information Technology, Department of Science Strategy and Development

Collection/compilation type: Government biotechnology data collection (questionnaire).

Variables:

- R&D expenditures
- Human resources
- Revenues
- Patent applications
- Number of companies.

Scope: Business enterprises and research institutes.

Frequency: Regular, the first time in 2004 (reference year 2003).

Periodicity: Annual.

Classification used: The indicators in the survey are classified by application sector; nine categories were chosen (health, agriculture and food processing, environment, forest products, bio-informatics, mining/energy/petroleum/chemicals, aquaculture and other).

Definition used: OECD definition of biotechnology.

Output: Results expected by the end 2004.

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): New collections in 2005 and 2006.

Contact details: <u>http://www.mnii.gov.pl/</u>

PORTUGAL

Collection/compilation agency: Observatório da Ciência e do Ensino Superior

Contact comments: No data on biotechnology are collected.

Contact details: <u>http://www.oces.mces.pt</u>

SLOVAK REPUBLIC

Collection/compilation agency: Statistical Office of the Slovak Republic

Contact comments: No data on biotechnology are collected at the moment. However, the Statistical Office of the Slovak Republic is exploring the possibility of adding a question, as per the *Frascati Manual* recommendation, on the percentage of R&D expenditure attributable to biotechnology to their 2005 R&D survey.

Contact details: http://www.statistics.sk

SOUTH AFRICA

Collection/compilation agency: Department of Science and Technology (DST)

Collection/compilation type: Audit of the South African biotechnology sector.

Variables:

Enterprise:

- Ownership structure
- Employees
- Business activities and product information
- R&D information
- Intellectual Property
- Technology platforms
- Support services.

Funders:

Investments.

Research group:

- Employees
- Biotechnology-related research
- Business activities and product information
- Intellectual Property
- Technology platforms
- Support services.

Scope: Non-governmental organization, companies, close corporation, para-statal, trust, higher education institute, other.

Frequency: Onetime in 2003.

Periodicity: N/A

Classification used:

- Human Health
- Animal Health
- Plant Biotech

- Industrial
- Environmental
- Food/Beverage
- Support Services
- Other.

Biotechnology activity is divided into 4 categories.

- First generation biotechnology involves the use of wild type or natural biological organisms to produce a product, for example, the use of yeast to make beer or wine.
- Second generation biotechnology refers to the production of specific products using a pure cell or tissue culture of organisms that have been specifically selected, through random cross-breeding or similar techniques, for their superior production or expression abilities without introducing foreign DNA.
- Third generation biotechnology involves manipulation of the genetic make-up of organisms, by introducing selected foreign (across the species barrier) DNA, through recombinant DNA technology, to make them produce small molecules, compounds or proteins.
- Support services for biotechnology include those activities that do not directly make use of biotechnology activities but provide essential support to those groups that do, *e.g.* legal services, business and financial support, equipment or reagent supplies, etc.

Definition used: Organizations "using biotechnology" are those that use a set of techniques leading to the transformation of a substance or production of a product, and where living organisms, or parts thereof, are involved. The living material may be the object that is transformed or produced or may be used in the manipulation or production process.

DNA: Genomics, Bioinformatics, Pharmaco-genomics, Gene probes/DNA markers, DNA Sequencing/ Synthesis/Amplification, Recombinant DNA technologies, Transgenesis.

Proteins and Molecules: Peptide/Protein Sequencing/Synthesis, Lipid/protein engineering, Carbohydrate engineering, Proteomics, Enzymology, Hormones and growth factors, Cell Receptors/Signaling/ Pheromones, Antibodies, Structural Biology, Molecular modelling.

Cell and Tissue Culture and Engineering: Cell/tissue culture, Tissue engineering, Hybridization, Cellular fusion, Vaccines/Immune Stimulants, Embryo manipulation.

Process Biotechnologies: Fermentation, Bioreactors, Bioprocessing, Biotransformation, Bioleaching, Biopulping, Bio-bleaching, Biodesulphurization, Bioremediation, Biofiltration, Phytoremediation, Biological gas cleaning, Bioaugmentation, Bioindicators, Process Control, Classical/Traditional Breeding, Extraction/Purification/Separation.

Sub-cellular Organisms: Viral vectors, Gene therapy.

Other: Molecular High Throughput Screening, Drug Delivery, Rational Drug Design, Diagnostics, Biochips, Combinatorial Chemistry, Biomaterials, Processing of Blood Products and Substitutes, Natural Products Chemistry, Microbiology/Virology/Microbial Ecology, Biosensors, Transgenics, Bio-nanotechnology, Molecular Synthesis.

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Output: http://www.egolibio.co.za/pages/audit.htm

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): A desktop study to determine SA Biotechnology Facts and Figures, Strengths and Weaknesses and Innovation Successes; Possible Survey on Public Understanding of Biotechnology.

Contact details: http://www.dst.gov.za/

Survey attached in annex:

- Survey for companies
- Survey for research
- Survey for biotechnology funders.

1. SPAIN

Collection/compilation agency: Instituto Nacional de Estadística (INE)

Collection/compilation type: Biotechnology survey.

Variables:

- Number of units enrolled in research and/or production related to biotechnology, by type of technology
- Human resources devoted to biotechnology:
 - Number of people employed in the production of biotechnology products
 - Number of researchers in biotechnology (both broken down by gender and in headcount and full-time equivalents)
- Economical resources devoted to research in biotechnology, broken down by type of expenditure and source of funds.

Scope: Business enterprise sector, government sector, higher education sector and the private non-profit sector.

Frequency: The survey will be launched in 2004. The preliminary results will be available in December.

Periodicity: Annual.

Classification used: For the business enterprise sector, data can be classified by activity (according to NACE-93 classification).

Definition used: OECD definition of biotechnology.

Output: Results are expected to be included in the publication of Statistics about R&D activities, a special publication may also be envisaged.

Contact comments: After the 2003 OECD Ad hoc Biotechnology Statistics Meeting, INE decided to launch a short questionnaire with the aim of collecting statistical information related to biotechnology. This questionnaire was prepared on the basis of the model survey proposed at the OECD meeting. This model survey was adapted to Spanish standards and will be enclosed as an annex to the Innovation survey and the R&D survey.

INE compiled a directory of 'biotechnology enterprises' (that can potentially develop and produce biotechnology products or be involved in biotechnology R&D). For this purpose INE used different sources (among them, a filter question included in the Innovation and R&D surveys which inquires about biotechnology-related activities in the enterprise). INE identified around 200 firms potentially linked to biotechnology activities and these will receive the biotechnology use questionnaire in attachment to the Innovation survey.

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To study the use of biotechnology in the rest of economical sectors, INE plans to send the biotechnology use questionnaire to all units in the government sector, higher education sector and the private non-profit sector covered by the R&D directory.

Data compilation began in May 2004 and first results will be available in December.

Future plans (plans for new collections, strategies, experiences etc.): On the basis of the results and experience of this first pilot survey, INE plans to improve the statistical study on the use of biotechnology, in terms of accuracy and scope.

Contact details: http://www.ine.es

Survey attached in annex

2. SPAIN

Collection/compilation agency: Genoma España (Spanish Foundation for the Development of Genomics and Proteomics)

Collection/compilation type: Genoma España uses a combination of methods to collect data: some data are collected by the Genoma España technology transfer survey; other science and technology indicators are compiled by using public data collected by the national and/or regional governments, and where necessary other sources are used to complement these data.

Variables:

1. Science and Technology Indicators (by sector, year and region):

- National and regional expenditure on biotechnology in R&D:
 - o Grants for researchers
 - o Grants for firms
 - o Grants for scientific infrastructure.
- European Framework Programme in R&D: Grants for Spanish biotechnology researchers.
- Universities and Public Research Organizations technology transfer indicators:
 - o Joint projects
 - o Patents
 - o Economic impacts
- Number of patents applications and patents granted
- Different bibliometric indicators in biotechnology.
- 2. Industry Indicators (by sector, year and region):
 - Number of Biotechnology firms
 - Number of employees
 - Biotechnology R&D private expenditure
 - Turnover of Spanish biotechnology firms
 - Venture capital investment.
- 3. Public Perception Indicators:
 - Eurobarometer
 - Media publication analysis
 - Biotechnology knowledge.

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Scope: National and regional governments, universities, public research organizations, business enterprise, and media.

Frequency: Annual.

Periodicity: Annual.

Classification used:

- Human health
- Animal health
- Agriculture, livestock and fisheries
- Food
- Environment
- Bioprocessing
- Technology development.

Definition used: OECD definition of biotechnology.

Output: Avance del Estudio Estratégico de la Biotecnología en España: Descripción e Indicadores, 2003, February 2004 (only in Spanish).

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): Updating of information and indicators to characterize the Spanish biotechnology sector. Establish future economic scenarios for Spanish biotechnology using an econometric model.

Contact details: www.gen-es.org

1. SWEDEN

Collection/compilation agency: Statistics Sweden (SCB)

Collection/compilation type: R&D survey.

Variables:

- R&D personnel (full-time equivalent)
- R&D expenditure.

Scope: Business enterprise sector, government sector, higher education sector.

Frequency: Biennial.

Periodicity: Annual.

Classification used: N/A

Definition used: No explicit definition is given in the national R&D survey; however, the OECD definition will be incorporated in future surveys.

Output:

Research and Experimental development in the Business Enterprise Sector 2001 (in Swedish) Research and Experimental Development in the Higher Education Sector 2001 (in Swedish) Research and Experimental Development in the General Government Sector 2001 (in Swedish).

Contact comments: Data are available for 1997, 1999 and 2001.

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: <u>www.scb.se</u>

2. SWEDEN

Collection/compilation agency: VINNOVA (Swedish Agency for Innovation Systems)

Collection/compilation type: Analysis of innovation system

Variables:

For firms:

- Business field
- Number of employees
- Turnover
- Equity-to-assets ratio
- Net profits/losses
- Year.

For publications and patents:

- Organization
- Scientific or technical field
- Number
- Year.

Scope: Firms, universities and university hospitals, research institutes.

In earlier studies, the focus of the analysis of industry has been on Dedicated Biotech Firms. In the studies currently underway also large pharmaceutical companies and other large bio-related firms are included.

Frequency: Reports published in 2001 and 2003.

Periodicity: No fixed schedule.

Classification used:

In the report from 2003 the following classifications were used.

Lines of business for industry:

- Pharmaceuticals & medicine (drug development, diagnostics etc)
- Agrobiotechnology (genetically modified plants, biological plant protection)
- Environmental biotechnology (soil, waste, and water treatment)
- Biotechnology tools & supplies (processes, equipment and instruments for biotechnological use)

- Functional food and feed (mainly probiotics)
- Bioproduction (biomolecular or micro-organism production).

For scientific publications:

- Biochemistry & Molecular biology
- Biophysics
- Biotechnology & Applied microbiology
- Cell biology
- Medicinal chemistry
- Genetics & Heredity
- Immunology
- Microbiology
- Neurosciences
- Virology
- Biomedical engineering (different from the other fields this is not core biotechnology).

For patents (much broader than biotechnology):

- Medical electronics
- Medical equipment
- Biotechnology
- Pharmaceuticals.

In work started in 2004 (see below), mapping of industry will also include medical equipment and fields of scientific publications and will look more broadly at medical sciences as well as some other bio-related fields not included in core biotechnology.

Definition used:

For lines of business: See Classification above, this is unavoidably a somewhat subjective classification. The reports provide a list of all the companies and their lines of business classification.

For fields of science: Selected ISI Journal categories (See Classification).

For patent fields: Selected IPC classes:

Code US patent class

- 424 Drug, Bio-Affecting and Body Treating Compositions
- **426** Food or Edible Material: Processes, Compositions, and Products
- 435 Chemistry: Molecular Biology and Microbiology
- **436** Chemistry: Analytical and Immunological Testing

- **514** Drug, Bio-Affecting and Body Treating Compositions
- **530** Chemistry: Natural Resins or Derivatives; Peptides or Proteins; Lignins or Reaction Products Thereof
- 800 Multicellular Living Organisms and Unmodified Parts Thereof
- **930** Peptide or Protein Sequence
- 935 Genetic Engineering: Recombinant DNA Technology, Hybrid or Fused Cell Technology, and Related Manipulations of Nucleic Acids

Output:

Anna Sandström, IVA and Lennart Norgren, VINNOVA, *Swedish Biotechnology - Scientific Publications*, *Patenting and Industrial Development*, VINNOVA Analysis VA 2003:2, Stockholm April 2003 http://www.vinnova.se/main.aspx?ID=7E711701-82DA-431B-BB64-3DF4942A95F8

A. Sandström et al, *The Swedish biotechnology innovation system*, VINNOVA, VF 2001:2, Stockholm 2001

http://www.vinnova.se/main.aspx?ID=06FAD169-76AE-45DB-A0D4-115B4D189F11

Contact comments:

The biotechnology work previously carried out by NUTEK is now done by the Swedish Agency for Innovation Systems (VINNOVA). VINNOVA was established in 2001 by combining the Technology Division of NUTEK, the Swedish Transport & Communications Research Board (KFB) and part of the Swedish Council for Work Life Research (RALF).

VINNOVA aims at providing policy-relevant information and analysis of the Swedish Biotechnology Innovation System in its international context. For this purpose any relevant information source will be utilized.

For analysis of biotechnology and related industries, the identification and classification of relevant firms is seen as a major bottleneck, and VINNOVA has devoted special attention to this issue. Recently cooperation with regional organizations has become important in this context. Additional data for the identified firms have mainly been derived from administrative records, *e.g.* the annual records that companies are obliged to submit to the Swedish Patent and Registration Office. VINNOVA did not administer a special biotechnology firm survey.

Future plans (plans for new collections, strategies, experiences, etc.):

1. Firms in biotechnology, pharmaceuticals and medical technology:

In 2004, VINNOVA in collaboration with regional organizations is undertaking a mapping of Swedish firms working in the areas of biotechnology, pharmaceuticals and medical technology. Each regional organization is identifying relevant firms in their region and gathering data on the number of employees in 2003. With the help of consultants, firms are categorized according to business field and certain other parameters. For biotechnology firms, employment in 1997 and 2003 will be compared. The project is expected to be completed during 2004. Comparison with other countries is actively sought. With Statistics Sweden, VINNOVA will separately explore the possibility of using existing databases to further characterize Swedish biotechnology and related firms, e g in terms of the educational level of employees, mobility of personnel, and exports.

2. International comparisons of scientific publications in Bioregions:

In cooperation with the Swedish Research Council, VINNOVA has started an analysis of scientific publications in fields related to life sciences and biotechnology aiming at comparing Bioregions in Sweden with their counterparts in other countries. Data from ISI's Science Citation Index for the period 1985-2003 will be used. In the first stage, only the number of publications will be studied. The distribution of publications between fields (as defined by groups of journals) and individual research organizations will be analysed as well as changes in both respects over time. Research organizations will be grouped according to the regions in which they are located. Around 400 publications with high Impact factors in their respective fields will be selected from ISI's database. Swedish Bioregions will be compared with 5-10 leading Bioregions in other countries.

Other plans:

Additional quantitative studies of the Swedish Biotechnology Innovation System are likely to be initiated by VINNOVA during 2004 or 2005. The greatest need appears to be for placing the Swedish situation in its international context. Comparisons of Bioregions may here be the most fruitful approach as such comparisons can be meaningful even between regions in countries of very different size. Such comparisons of Bioregions would ideally combine hard quantitative data with more qualitative observations.

There is a lack of reliable international comparisons of government and other funding of research in biotechnology and related disciplines. VINNOVA will actively look for partners in other countries interested in working together to develop such comparative analysis.

Contact details: <u>http://www.vinnova.se</u>

3. SWEDEN

Collection/compilation agency: NUTEK (Swedish National Board for Industrial and Technical Development)

Collection/compilation type: Mainly administrative records.

Variables:

- Swedish patenting in the US patent system (1986-97 could be extended to 1999)
- Data on Swedish scientific publications (SCI) (1986-98 could be extended to 1999)
- Lists of Swedish companies with biotechnology activities categorised according to their business and some data on their number of employees and turnover (1996-99 or 1996-98)
- Public/semi-public financing of biotechnology research (1997)
- Public seed financing (1997-99)
- Swedish venture capital companies investments in biotechnology industry (1999)
- The results of a questionnaire sent to the identified companies. The questionnaire mostly concerns collaboration with universities and other companies and driving forces and obstacles for innovations and growth in Sweden.

Scope: Firms, industrial research institutes, public research organisations and higher education.

Frequency: The project started January 1999 and will end January 2001 unless new funding is found. The time periods covered are listed under Variables and Output.

Periodicity: See above.

Classification used:

Patents: A broad selection of patents using the classification system of the US Patent and Trademark Office was made according to the table below (Table 1). This selection was subsequently refined by using a new classification system (Table 2) thus omitting many patents identified in the initial selection.

Code	US Patent Class	
424	Drug, Bio-Affecting and Body Treating Compositions	
426	Food or Edible Material: Processes, Compositions, and Products	
435	Chemistry: Molecular Biology and Microbiology	
436	Chemistry: Analytical and Immunological Testing	
514	Drug, Bio-Affecting and Body Treating Compositions	
530	Chemistry: Natural Resins or Derivatives; Peptides or Proteins; Lignins or Reaction Products Thereof	
800	Multicellular Living Organisms and Unmodified Parts Thereof	
930	Peptide or Protein Sequence	
935	Genetic Engineering: Recombinant DNA Technology, Hybrid or Fused Cell Technology, and Related Manipulations of Nucleic Acids	

Table 1. US Patent Class

Classification System for Biotechnology and Biotechnology-related patents				
CLASSIFICATION	EXPLANATION OR EXAMPLES			
Agriculture				
Agricultural technique	<i>E.g.</i> egg inoculation with living cells of micro-organism, feed optimisation genetics, plant protection using micro-organisms.			
Animal food	<i>E.g.</i> food additives such as growth hormones and bacteria.			
Bioprocess				
Process	Production of chemicals (<i>e.g.</i> ethanol, carbohydrates, epoxy compound esterification of glycosides etc) using bioprocesses.			
Food				
Functional food	<i>E.g.</i> enzyme or bacteria addition to food stuff.			
Food technique	<i>E.g.</i> protein treatment, enzyme stabilisation in feed stuff, way of adding biologically active materials to foodstuff.			
Wood, pulp and paper				
Wood, pulp or paper treatment	<i>E.g.</i> enzyme production for pulp treatment, biocides such as a pheromone, wood protection against fungi.			
Biotechnology supplies				
Process	<i>E.g.</i> biomolecular production and analysis, bioseparation, DNA sequencing, etc.			
Laboratory equipment	Equipment for use specifically on biological systems.			
Genomics and functional genomics	E.g. cloning, expression control, vectors, recombinant DNA techniques.			
Biosensors	E.g. biomolecules- detection and/or analysis.			
Transgenic animal	Animal model for helicobacter pylori infection.			
Medical Technique				
Tissue treatment	<i>E.g.</i> removing micro-organisms from tissue and cleaning tissue using biomolecules, implant technique, dental technique, wound treatment, blood-collecting technique.			
Pharmaceuticals and medicine				
Drugs and their preparation	Pharmaceuticals and vaccines for man or animal, consisting of biomolecules of micro-organisms and their preparation.			
Drug delivery systems	Drug delivery systems for biopharmaceuticals.			
Diagnostics	Includes biomolecular diagnostics, immunoassays and antibodies.			
Chemistry	1			
New or improved chemical or process	<i>E.g.</i> chemical synthesis, column material, separation and detection techniques surfactants and cosmetic formulations as well as probable drugs and drug formulations (but not specified as such).			

CLASSIFICATION	EXPLANATION OR EXAMPLES
Environmental	
Environmental technique	<i>E.g.</i> wastewater treatment and analysis.
Food	
Functional food	E.g. addition of trace elements to foodstuff, "health drinks", dietary fibres, etc.
Food technique	E.g. milk treatment, fibre-production.
Quality control	E.g. control of microflora.
Wood, pulp and paper	
Wood, pulp or paper treatment	<i>E.g.</i> lignin preparation, bleaching of pulp.
Laboratory technique	
Laboratory equipment	Equipment for general laboratory use.
Medical Technique	
Contrast agents	<i>E.g.</i> for magnetic resonance imaging or X-ray.
Biological fluids	Blood plasma substitute or blood plasma treatment method (<i>e.g.</i> intravenous infusion for blood pressure control and re-administration of treated plasma) nutrient solutions for intravenous administration, blood material treatment and saliva substitute.
Wound treatment	E.g. sore cleansing and dressings.
Tissue treatment	<i>E.g.</i> adhesion prevention or promotion and implant preparation.
Other	<i>E.g.</i> eye-surgical method, device of biocompatible material, sperm separation ointments and pastes for controlling micro-organisms.
Pharmaceuticals and medicine)
Drugs and their preparation	New drugs and new drug compositions.
Drug delivery systems	Drug delivery systems and galenic pharmacy.
Diagnostics	Diagnostics not fitting the previous diagnostics description, e.g. patch test o allergy.

Scientific publications: The journal categories developed by the Institute for Scientific Information (ISI, Philadelphia, United States) were used. Included are the categories in Table 3 (*cf.* the first report under output for more information).

Table	3
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CQ	Biochemistry & molecular biology
DA	Biophysics
DB	Biotechnology & applied microbiology
DR	Cell biology
DX	Chemistry, medical
MB	Mathematical methods, biology & medicine
NI	Immunology
QE	Materials science, biomaterials
QU	Microbiology
RU	Neuroscience
ZE	Virology

Industry: Companies having activities according to our chosen definition were categorised into the following categories: Pharmaceuticals and medicine (drug development, diagnostics, etc); Agrobiotechnology (GMO, biological plant protection, etc); Environmental biotechnology (bioremediation, waste treatment); Biotechnology supplies (instruments and equipment for bioseparation and analyses); Functional food (mainly probiotics); Bioproduction (biomolecular or microorganism production).

Definition used: An analysis of the Swedish Biotechnology Innovation System, is being undertaken, *i.e.* The actors that develop, produce, analyse or use biological systems on a micro-, cellular or molecular level and the public and private institutions that affect their behaviour.

The focus is on modern biotechnology and innovative use of classical biotechnology.

Output: In English:

NUTEK, A study of the Swedish biotechnology innovation system using bibliometry, January 2000.

Contact comments: The biotechnology work previously carried out by NUTEK is now done by the Swedish Agency for Innovation Systems (VINNOVA).

Contact details: <u>http://www.nutek.se/</u>

4. SWEDEN, NORWAY, DENMARK

Collection/compilation agency: Business Region Göteborg, Karolinska Institutet, MedCoast Scandinavia, Medicon Valley Academy, ScanBalt, Stockholm BioRegion, SwedenBIO and Uppsala BIO.

Collection/compilation type: Database with statistics collected directly from (or directly updated by) companies.

Variables:

- Contact details
- Year of establishment
- Keywords
- Description.

Scope: Scandinavian Life Science Industry (currently: Sweden, Norway & Denmark).

Frequency: Continuous.

Periodicity: Annual.

Classification used: R&D, marketing/selling, financing, service, production.

Definition used: N/A

Output: http://www.scandinavianlifescience.org

Contact comments: To further strengthen Scandinavia as a world-leading region in Life Science/biomedicine the leading regional actors in Scandinavia are now joining forces. As a first step we are establishing the Scandinavian Life Science Database - a comprehensive database of Scandinavian companies active in the Life Science area. This joint database will be a powerful tool and replace earlier regional databases.

Number of companies in the database	1 196
Number of Karolinska Institutet companies	47
Number of MedCoast companies	343
Number of Medicon Valley companies	202
Number of Stockholm BioRegion companies	351
Number of SwedenBio companies	149

For more information and contacts please consult the Web site.

Contact details: http://www.scandinavianlifescience.org

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1. SWITZERLAND

Collection/compilation agency: Swiss Federal Statistics Office

Collection/compilation type: R&D Survey.

Variables: R&D objectives: percent spent on biotechnology.

Scope: Private enterprises.

Frequency: One question was incorporated in the 2000 R&D survey.

Periodicity: Every four years, as the R&D survey. Next survey: 2004 R&D survey. As of 2004, the R&D survey will be conducted every two years.

Classification used: Same as the R&D survey, as the biotechnology element is a part of the survey.

Definition used: In the 2004 R&D survey, we will use the official OECD definition of biotechnology, followed by a list of possible activities in Biotechnology for the requested fields.

Output: Results of the 2000 R&D survey were published in 2001: Économie suisse/OFS, *La recherche et le développement dans l'économie privée en Suisse, 2000,* Zürich, Neuchâtel, 2001.

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): The question incorporated in the 2000 R&D survey will be incorporated in the 2004 R&D survey.

Contact details: http://www.statistik.admin.ch/

Survey attached in annex

2. SWITZERLAND

Collection/compilation agency: Eidgenössisches Institut für Geistiges Eigentum/Institut Fédéral de la Propriété Intellectuelle/Istituto Federale della Proprietà Intellettuale/Swiss Federal Institute of Intellectual Property

Collection/compilation type: Biotechnology patenting survey.

Variables: Qualitative patenting data (assessment scale 1-5).

Scope: Biotechnology entities (private and public) in Switzerland.

Frequency: 1.questionnaire: 53 questions; 2. questionnaire: 33 questions.

Periodicity: Only once, 1. questionnaire: March 2003, 2. questionnaire: September 2003.

Classification used: N/A

Definition used: Biotechnology companies according to the yearbook of the Swiss Biotechnology Federation and the Swiss Life Sciences Database <u>http://www.swisslifesciences.ch/page/index.html</u>

Output: Final report published: 'Research and Patenting in Biotechnology; A Survey in Switzerland' Bern 2003, <u>http://www.ige.ch/E/jurinfo/j100.htm#2</u>

Contact comments: Nikolaus Thumm, nikolaus.thumm@ipi.ch

Contact details: http://www.ige.ch/E/jurinfo/j100.htm#2

Future plans (plans for new collections, strategies, experiences etc.): The survey has been a unique exercise accompanying the ongoing Patent Law Reform in Switzerland.

Contact details: http://www.ige.ch/E/jurinfo/j100.htm#2

3. SWITZERLAND

Collection/compilation agency: IPMZ - Institute of Mass Communication and Media Research, University of Zurich

Collection/compilation type: Survey of Swiss Population (German, French, Italian region) (EUROBAROMETER).

Variables: A range of survey questions on public perception of biotechnology, including knowledge questions.

Scope: Analysis of public perceptions of biotechnology, in combination with a media content analysis.

Frequency: Three surveys in 1997, 2000 and 2003.

Periodicity: See frequency.

Classification used: see description of the Swiss projects (including data sets):

http://www.sidos.ch/fw_query/siweb2.fwx?htm.sel0=6332

http://www.sidos.ch/fw_query/siweb2.fwx?htm.sel0=7771

Description of the European project:

http://www.lse.ac.uk/Depts/lses/

Definition used: See Classification used.

Output: Publications: See Classification used.

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): The project is terminated. Currently, there are no plans for further data collection.

Contact details:

Swiss project (Contact persons: Prof. Heinz Bonfadelli, Dr. Urs Dahinden):

http://www.ipmz.unizh.ch/home.html?/service/index.html

European project:

http://www.lse.ac.uk/Depts/lses/

TURKEY

Collection/compilation agency: State Institute of Statistics (SIS)

Comments: No data on biotechnology are collected.

Contact details: http://www.die.gov.tr/

1. UNITED KINGDOM

Collection/compilation agency: Office of National Statistics (ONS)

Collection/compilation type: Government R&D Survey.

Variables: Budget previsions of central governmental R&D expenditure.

Scope: Government sector.

Frequency: Annual. Data are available from 1993 onwards.

Periodicity: Annual.

Classification used: A NABS (Nomenclature for the Analysis and Comparison of Scientific Programmes and Budgets) analysis of net R&D expenditure – further broken down into biotechnology, information technology, international collaborative projects and payments to firms.

Definition used: Biotechnology is defined as the application of biological organisms, systems and processes to manufacturing or service industries.

Output: N/A

Contact comments: These data are supplied to EUROSTAT.

Contact details: http://www.statistics.gov.uk/

2. UNITED KINGDOM

Collection/compilation agency: Critical I on behalf of the UK Department of Trade and Industry

Collection/compilation type: Statistical survey incorporating information gathered directly from companies, and from market research, annual reports and other information sources.

Variables:

For sector overall and by sub-sector:

- Number of companies
- Age of company
- Number of employees
- Product development pipeline
- Market capitalisation
- R&D spend
- Revenues by category
- Finance raised.

Scope: Private sector biotechnology companies in the United Kingdom.

Frequency: Annual.

Periodicity: Annual.

Classification used: See Definition used.

Definition used: The categories used are:

Agbio	Animal Healthcare, Biopesticides, Crop Agriculture and food technology
Biodiagnostics	Environmental Diagnostics, Healthcare diagnostics, Industrial Diagnostics
Environmental	Biocleaning, Bioremediation, Water and effluent treatment, waste recycling
Human Healthcare	Biomaterials, Drug Delivery, Drug Discovery, Gene Therapy, Genomics, Vaccines
Technology Service Providers	Bioinformatics, Functional Genomics, High Throughput screening
Service providers	Bioprocessing, Chemicals, Contract Research, Contract Manufacturing

Biotechnology is defined as "those companies whose primary commercial activity depends on the application of biological organisms, systems or processes, or on the provision of specialist services to facilitate the understanding thereof."

Output: Forthcoming, *Critical I report to the Department of Trade and Industry, 2004* (working title) with data up to the end of 2002.

Contact comments: Critical I use the methodology that was originally developed by Arthur Andersen and used in a series of reports in the 1990s.

Contact details: Department of Trade and Industry, Bioscience Unit <u>http://www.dti.gov.uk/sectors_biotechnology.html</u>

1. UNITED STATES

Collection/compilation agency: The National Science Foundation (NSF) (sponsor) and U.S. Census Bureau (collection agent)

Collection/compilation type: Survey of Industrial Research and Development.

Variables:

- R&D expenditure
- Percentage of biotechnology R&D expenditure attributable to nanotechnology.

Scope: For-profit industrial firms with five or more employees that perform R&D in the 50 US states or D.C.

Frequency: Annual since 2001.

Periodicity: Annual.

Classification used: N/A for biotechnology data collection itself. Generally, statistics resulting from the data collection are classified by the performing firms' North American Industrial Classification System (NAICS) code, size (based on number of employees), location (US state or country) of R&D performance, character of work, source of funding, and other classifiers.

Definition used: Biotechnology is the application of science and technology to living organisms, as well as parts, products, and models thereof, to alter living or nonliving materials for the production of knowledge, goods, and services including:

- DNA technologies such as:
 - Genomics
 - Pharmacogenetics
 - Gene probes
 - DNA sequencing/synthesis/amplification
 - Genetic engineering
- Protein and molecular technologies such as:
 - Protein/peptide sequencing/synthesis
 - Lipid/protein glycoengineering
 - Proteomics
 - Hormones
 - Growth factors
 - Cell receptors/signaling/ pheromones
- Cell and tissue culture and engineering including:
 - Cell/tissue culture
 - Tissue engineering
 - Hybridization
 - Cellular fusion
 - Vaccine/immune stimulants
 - Embryo manipulation

- Process biotechnologies such as:
 - Bioreactors
 - Fermentation
 - Bioprocessing
 - Bioleaching
 - Biopulping
 - Biobleaching
 - Biodesulphurization
 - Bioremediation
 - Biofiltration
- Subcellular organism research including:
 - Gene therapy
 - Viral vectors
- Other biotechnology areas such as:
 - Bioinformatics
 - Nanobiotechnologies

Output: Tabulations in the annual report series *Research and Development in Industry* containing biotechnology R&D expenditures by industry and size of company (based on number of employees) and the percentage of biotechnology R&D expenditures attributable to nanotechnology.

Contact comments: Biotechnology R&D data are not extensively available from official statistics. Government agencies, including the National Science Foundation (NSF) and the U.S. Census Bureau, are not able to document industry's biotechnology R&D activities in greater detail for a variety of reasons, the most important being that biotechnology is not a separate industry code in the government's North American Industrial Classification System (NAICS) system.

Future plans (plans for new collections, strategies, experiences etc.): Current level of data collection will be maintained while research into quality and utility of resulting statistics are evaluated.

Contact details:

http://www.nsf.gov

http://www.nsf.gov/sbe/srs/stats.htm

http://www.nsf.gov/sbe/srs/indus/start.htm

http://www.nsf.gov/sbe/srs/seind02/start.htm

Latest survey forms and instructions: The 2003 versions of the Form RD-1, Form RD-1A, and their instructions are available at: <u>http://www.nsf.gov/sbe/srs/sird/start.htm</u>.

2. UNITED STATES

Collection/compilation agency: US Department of Commerce, Technology Administration and Bureau of Industry and Security

Collection/compilation type: Survey of US firms engaged in biotechnology activities, 2002.

Variables:

- Application focus, research activities and North American Industry Classification System codes
- Demographic characteristics (*e.g.* location of operations and ownership)
- Financial operations and investment (*e.g.* sales, operating costs and income, capital investments and export revenues)
- Research and development expenditures and intellectual property protection
- Employment (*e.g.*, FTEs, occupations and foreign outsourcing)
- Interactions with federal agencies (*e.g.*, participation in government programs and contracting)
- Impediments to business growth
- Market and business conditions and projections.

Scope: Survey data were collected from companies that engage in biotechnology research, create biotechnology products or research tools, and/or use biotechnology processes in their manufacturing - either as one of several business lines or as their sole business. Respondents whose business activities appeared to differ from the survey's definition of biotechnology were not included in the final analysis. (See definition below).

Data were obtained from public and privately traded companies and non-profit enterprises operating domestically that identified themselves as biotechnology firms or organizations. The survey was mailed to both US and foreign-owned businesses existing within the United States. Excluded from this study are government organizations, universities, and foreign businesses operating abroad.

Frequency: The survey was conducted in summer/fall of 2002.

Periodicity: N/A

Classification used: N/A

Definition used: Biotechnology was defined as the application of molecular and cellular processes to solve problems, conduct research, and create goods and services. It includes a diverse collection of technologies that manipulate cellular, sub-cellular, or molecular components in living things to make products or discover new knowledge about the molecular and genetic basis of life, or to modify plants, animals and micro-organisms to carry desired traits. Such technologies include, but are not limited to: genetic engineering (*e.g.* recombinant DNA, gene therapy, cloning, antisense); hybridoma technology (to produce monoclonal antibodies); polymerase chain reaction or PCR amplification; gene mapping; DNA sequencing; restriction fragment length polymorphism (RFLP) analysis; and protein engineering.

Output: The survey instrument and results were presented in a report entitled "A Survey of the Use of Biotechnology in U.S. Industry," November 2003.

See http://www.technology.gov/reports/Biotechnology/CD120a_0310.pdf

Contact comments: The Technology Administration, U.S. Department of Commerce, works to maximize technology's contribution to America's economic growth.

Future plans (plans for new collections, strategies, experiences etc.): It is uncertain whether future biotechnology surveys will be conducted.

Contact details: <u>http://www.technology.gov</u>

The survey is available in the publication at: http://www.technology.gov/reports/Biotechnology/CD120a_0310.pdf

3. UNITED STATES

Collection/compilation agency: Bureau of the Census, U.S. Department of Commerce

Collection/compilation type: Part of the 5-year Economic Census.

Variables:

- Number of establishments
- Total revenue
- Payroll
- Number of employees.

Various additional information:

- Class of customer
- Revenue by type of research activity.

These data are by industry and geographic location.

Scope: All operating business locations in the United States with paid employees.

Frequency: Every 5 years.

Periodicity: Covers a 12-month calendar year for years ending in 2 and 7.

Classification used: North American Industry Classification System (NAICS) category 541710.

Definition used: No definition used. Respondent self designates as engaged in "biotechnology research."

Output: Electronic data tables and database, print on demand.

Contact comments: N/A

Future plans (plans for new collections, strategies, experiences etc.): N/A

Contact details: www.census.gov

Copies of survey form PS-54109 available on: www.census.gov

EUROPEAN COMMISSION

Collection/compilation agency: European Commission

Collection/compilation type: Interviews or postal inquiries.

Variables:

- Public R&D spending
- Biotech-related programmes and sub-programmes
- Research infrastructure
- Participation in EU programmes
- Promotion of industry links
- Number of researchers
- Policy targets in relation to biotechnology
- Non-profit organisations involved in R&D etc.

Scope: Publicly-funded biotechnology R&D stimulation programmes in 17 European countries. Excluding research carried out at universities and private laboratories.

Frequency: Onetime study terminated in 1999.

Periodicity: Study covered the 1994-98 period.

Classification used: "The widely recognised OECD definition of biotechnology (The application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services) together with the European Federation of Biotechnology one ("The integrated use of natural sciences and engineering sciences by the application of biosystems – cells of microbial, plant and animal origin, parts thereof and molecular analogues – in bioindustries") have been used. However, some Member States might have applied different concepts, reflecting the various ways biotechnology is used in each country (EC, DGXII, *Biotechnology R&D in Europe: National Files*, 1996).

Output:

Inventory of Public Biotechnology R&D Programmes in Europe: Volume 1 - 1999: an analytical report.

Inventory of Public Biotechnology R&D Programmes in Europe: National Reports Volume 2. - 1999. Austria-Ireland.

Inventory of Public Biotechnology R&D Programmes in Europe: National Reports Volume 3. - 1999. Italy-United Kingdom + Index.

Contact comments:

Each national file, included in Volumes 2 and 3, is structured as follows:

- Background: setting the national scene

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- The national system for biotechnology funding: policy and instruments
- National competencies and priorities
- Public and private biotechnology infrastructure
- References and people interviewed.

http://europa.eu.int/comm/dg12/biotech/biot-pg-pdf.html

Future plans (plans for new collections, strategies, experiences etc.): Follow-up study BIOPOLIS to be started in autumn 2004, results expected end of 2005. Coverage: 30 European countries (14 EU Member States, 10 accession countries, 3 candidate countries, plus Norway, Iceland, and Switzerland). Time-span: 1999-2004. OECD methodology should be used as far as possible, while other kinds of data must be flagged as "not compliant".

EUROSTAT

Collection/compilation agency: EUROSTAT

Collection/compilation type: Survey on Government Budget Appropriations on R&D – GBAORD.

Variables: Research and Development: Government R&D Appropriations.

Scope: Government sector (appropriations).

Frequency: Annual.

Periodicity: Annual.

Classification used: NABS (Nomenclature for the Analysis and Comparison of Scientific Programmes and Budgets).

Output: NEWCRONOS database.

Contact comments: The following Member States report data on biotechnology: Denmark, Germany, Greece, Spain, Ireland, Italy, and the United Kingdom.

Contact details: http://europa.eu.int/comm/eurostat/