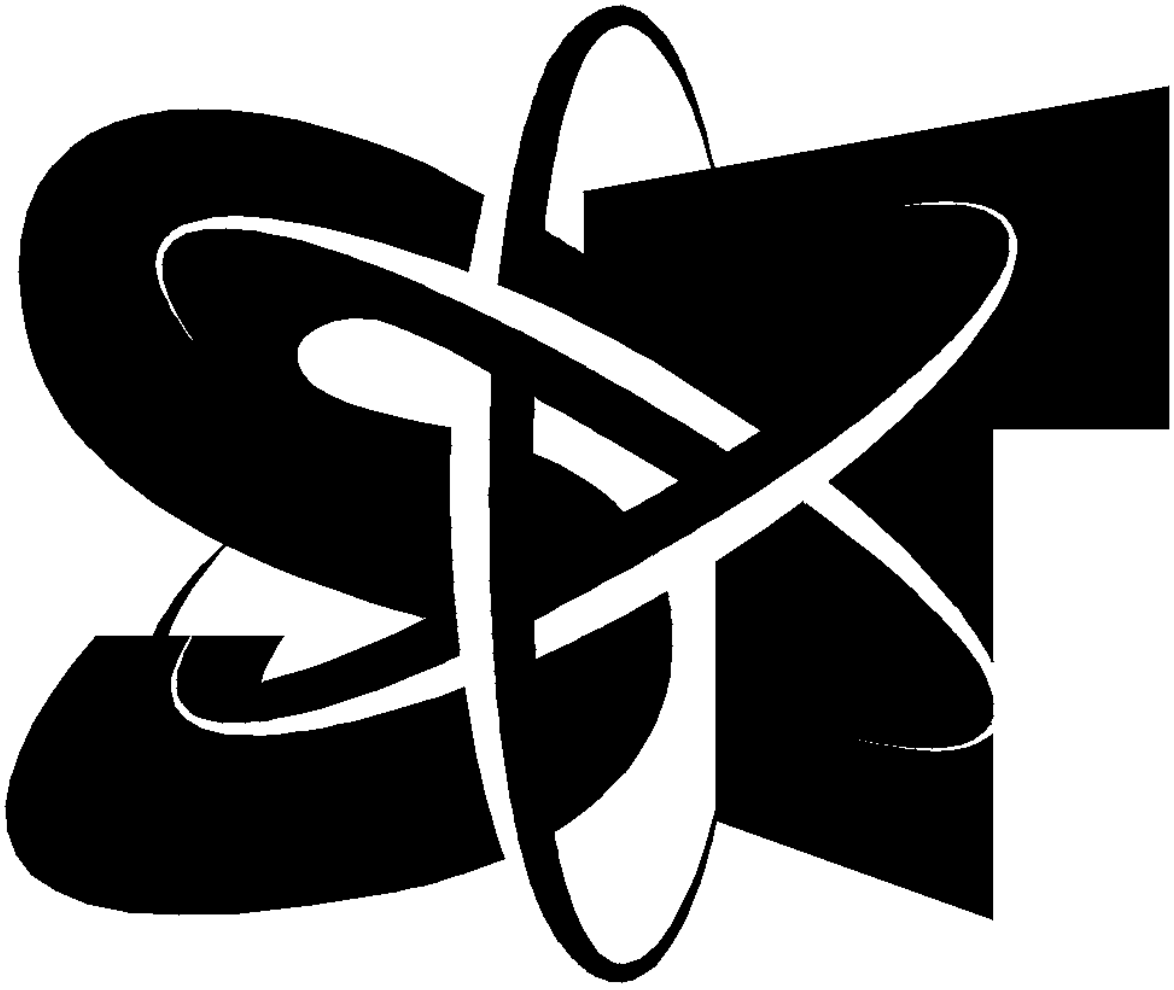
Science, Innovation and Electronic Information Division

RESEARCH PAPER

INTERNATIONNALLY COMPARABLE INDICATORS ON BIOTECHNOLOGY: A STOCKTAKING, A PROPOSAL FOR WORK AND SUPPORTING MATERIAL

W. Pattinson, B. Van Beuzekom and A. Wyckoff No. 9



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Canada

Internationally Comparable Indicators on Biotechnology: A Stocktaking, a Proposal for Work and Supporting Material

W. Pattinson, B. Van Beuzekom and A. Wyckoff

OECD

The content of this paper is entirely the responsibility of the authors and does not reflect the views of the OECD or its member countries.

Statistics Canada

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The Science and Innovation Information Program

The purpose of this program is to develop **useful indicators of science and technology activity** in Canada based on a framework that ties them together into a coherent picture. To achieve the purpose, statistical indicators are being developed in five key entities:

- **Actors**: are persons and institutions engaged in S&T activities. Measures include distinguishing R&D performers, identifying universities that license their technologies, and determining the field of study of graduates.

- **Activities**: include the creation, transmission or use of S&T knowledge including research and development, innovation, and use of technologies.

- **Linkages**: are the means by which S&T knowledge is transferred among actors. Measures include the flow of graduates to industries, the licensing of a university's technology to a company, co-authorship of scientific papers, the source of ideas for innovation in industry.

- **Outcomes**: are the medium-term consequences of activities. An outcome of an innovation in a firm may be more highly skilled jobs. An outcome of a firm adopting a new technology may be a greater market share for that firm.

- **Impacts**: are the longer-term consequences of activities, linkages and outcomes. Wireless tele phony is the result of many activities, linkages and outcomes. It has wide-ranging economic and social impacts such as increased connectedness.

The development of these indicators and their further elaboration is being done at Statistics Canada, in collaboration with other government departments and agencies, and a network of contractors.

Prior to the start of this work, the ongoing measurements of S&T activities were limited to the investment of money and human resources in research and development (R&D). For governments, there were also measures of related scientific activity (RSA) such as surveys and routine testing. These measures presented a limited picture of science and technology in Canada. More measures were needed to improve the picture.

Innovation makes firms competitive and we are continuing with our efforts to understand the characteristics of innovative and non-innovative firms, especially in the service sector that dominates the Canadian Economy. The capacity to innovate resides in people and measures are being developed of the characteristics of people in those industries that lead science and technology activity. In these same industries, measures are being made of the creation and the loss of jobs as part of understanding the impact of technological change.

The federal government is a principal player in science and technology in which it invests over five billion dollars each year. In the past, it has been possible to say only *how much* the federal government spends and *where* it spends it. Our report **Federal Scientific Activities, 1998 (Cat. No. 88-204)** first published socio-economic objectives indicators to show *what* the S&T money is spent on. As well as offering a basis for a public debate on the priorities of government spending, all of this information has been used to provide a context for performance reports of individual departments and agencies.

As of April 1999, the Program has been established as a part of Statistics Canada's Science, Innovation and Electronic Information Division.

The final version of the framework that guides the future elaboration of indicators was published in December, 1998 (**Science and Technology Activities and Impacts: A Framework for a Statistical Information System,** Cat. No. 88-522). The framework has given rise to **A Five-Year Strategic Plan for the**

Development of an Information System for Science and Technology (Cat. No. 88-523).

It is now possible to report on the Canadian system on science and technology and show the role of the federal government in that system.

Our working papers and research papers are available at no cost on the Statistics Canada Internet site at http://www.statcan.ca/english/research/scilist.htm.

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TABLE OF CONTENTS

INTERNATIONALLY COMPARABLE INDICATORS ON BIOTECHNOLOGY: A STOCKTAKING, A PROPOSAL FOR WORK AND SUPPORTING MATERIAL

Although work on measuring biotechnology is just beginning within a select number of countries, many policy makers and analysts are calling already for an international effort to co-ordinate this work so that the ensuing statistics and indicators maintain some level of international comparability. Given the early stage of this technology and all the other competing priorities for statistical work (*e.g.* on mature but important areas such as services), this demand may seem misplaced but it is reflective of 3 events that are quickly evolving on the world stage: 1) issues associated with the trade of goods and services that involve biotechnology; 2) the belief that biotechnology will be a source of economic growth and a factor that may determine the relative competitiveness of countries, and 3) the recognition that this technology is a "general purpose technology" where the impact will be felt widely across industries and countries, regardless of its origin. These issues imply that the nature of measurement needs to shift from private sector sources mainly concerned with market growth to public sources that can place biotechnology into a broader framework including international trade, innovation and productivity which entails the need to directly compare measures of biotechnology to other publicly generated data.

For these reasons and because it has been successful at co-ordinating the measurement of other conceptually and mechanically difficult areas such as research and development, innovation, and growth of the information society, the Organisation for Economic Co-operation and Development (OECD) was asked to explore the feasibility of compiling statistics and generating indicators of biotechnology for its Member countries. With the support of the Government of Canada, this paper presents an initial stocktaking of the current state of methodological and statistical work on biotechnology by identifying existing national statistics, compiling a set of definitions currently in use and surveying user needs as identified in a number of countries. While somewhat descriptive, this stocktaking represents a foundation upon which future work to achieve international standards and measures can be built.

Existing national statistics

To help assess the availability of data in OECD Member countries, a questionnaire was sent to assess the availability of statistics and indicators, the methodology used in collecting this data (particularly the definition of biotechnology used) and quantitative analyses undertaken on biotechnology. While this questionnaire was sent to government officials who attend OECD working parties related to these issues, they were asked to provide responses to these inquiries regardless of whether or not this work was performed by a government agency. Replies were received from 21 member countries. A summary of replies is available in Annex 1.

The most common form of official data collection came in respect of R&D data collected as a part of their national R&D surveys. Five countries – Australia, Canada, Denmark, Japan and the Netherlands – collect data in this way. The data items available, however, are very limited as they generally only relate to R&D expenditures and the human resource input to that R&D. Only two countries have specific biotechnology firm surveys – Canada and France. A third, New Zealand, is proposing to undertake a similar survey, (Pattinson et al.(2000). These surveys are quite detailed and measure many data items about the structure and performance of the firms using biotechnology processes, producing biotechnology goods and services or undertaking biotechnology research.

A start-off practice, undertaken by some national statistical offices, has been to commission consulting firms to undertake national audits of the biotechnology industry. This has notably been the case for Australia (Ernst & Young), Canada (Ernst & Young) and France (Arthur Andersen). In the case of the latter two, the national statistical offices subsequently refined the commissioned surveys, narrowing the sampled population as well as the statistical questions.

Leading consulting firms such as Ernst & Young and Arthur Andersen have, for many years, been producing reports that track developments in specific countries. These publications generally have a fairly broad scope. Ernst & Young, in particular, has produced reports for Europe, the U.S., Germany and Belgium

(forthcoming – in conjunction with the Belgian Biotech Association). The US report is in its 14th year of publication and the European in its 7th year. These consultant firms also compile data on indicators such as venture capital in some countries.

Some of the more prominent pharmaceutical and agricultural corporations, (Monsanto, Wellcome, Dupont, etc.) also provide a range of information and indicators about biotechnology on their Internet web sites. A non-exhaustive list of relevant web sites and publications is given in Pattinson et al. (2000).

Most countries have national biotechnology associations. These associations provide a forum, to bring together all the players involved in the biotechnology community. These are important sources of information because they maintain registers or directories of public and private enterprises. Biotechnology associations often work co-operatively with public sector organisations to provide statistical information. In Australia, for example, the online 1999 Directory was produced jointly by the Australian Biotechnology Association Ltd and the Australian Government Department of Industry, Science and Resources. In Japan, the Japanese Bio-industry Association conducts its own survey measuring a range of statistical indicators including the value of biotechnologically produced goods.

The European Commission produced an inventory of public biotechnology programmes in all countries participating in the EU biotechnology 4th Framework programme 1994-1998 (17 countries). These reports present inventories of "specific aspects of each programme and other policy instruments by which biotechnology has been stimulated and additional information with respect to the national conditions, policies and impacts, etc".

Hungary and Finland have also conducted evaluations or "audits" of the biotechnology sectors that have enabled the compilation of some statistical indicators in those countries.

In addition to this directly collected data, there is other information that becomes available as a result of administrative records, most notably being patents data (from national and international Patents offices) and international trade data, generally coming available from national Customs offices.

The statistical definition of biotechnology

The definition of biotechnology used by responding countries varied considerably, but by and large consisted of two types – one based on a set of words which describe the processes referred to, called a "single" definition and a list-based definition. Examples of both are given in Pattinson et al. (2000) Each has its uses and both are required for different statistical purposes.

A broad definition is useful for measuring biotechnology using existing surveys on R&D or industrial activity generally. But in addition to a single broad definition, sub-classifications need to be developed to enhance the value of any statistical outputs that would be derived. Such classifications may be part of existing classifications used in existing statistical practices, such as standard industrial classifications or socio-economic classifications, or may need to be developed specifically to enhance the understanding of biotechnology. This issue needs to be further taken up in the development of an overall statistical framework that incorporates, *inter alia*, definitions, data items and classifications.

The list approach is used in diffusion surveys such as those conducted by Canada and France. In general these list use a detailed set of biotechnological process, but they need to be sufficiently flexible, generic and broad, as growth in biotechnologies is so rapid that any fixed list would be quickly rendered obsolete.

User requirements

A prerequisite for the development of internationally comparable indicators is the preparation of a set of user requirements, specifying the policy issues which needed to be addressed and the indicators that might be useful for that assessment. An initial list could include the following indicators, each of which are discussed briefly below:

- R&D, innovation and linkages between sectors in national innovation systems.
- Human resources devoted to biotechnology.
- Stock of biotechnology human resources.
- Patents and citations.
- Venture capital.
- Biotechnology diffusion.
- Production and trade in biotechnology products.
- Structural information about biotechnology firms
- Business start-ups.

R&D, innovation and linkages between sectors in national innovation systems

This is a key area for biotechnology statistics. It is important to know about the amount of R&D that is being carried out, who is conducting it, who is funding the R&D, the purposes of the R&D, and similar indicators. Further it is important to understand how this R&D leads to innovation, in the form of new products and processes.

As with most R&D statistics, data is required about the expenditure on such R&D (and innovation) and the human resource inputs to it. It is also important to understand the linkages between the R&D, and the R&D firms, and other aspects on the innovation systems occurring within Member countries. In particular, the linkages between the different institutional sectors need to be identified and measured, particularly if these links extend beyond a country's borders.

One mechanism for integrating the measurement of into R&D and innovation surveys is to include it in the *Frascati (OECD 93)and Oslo (OECD 97)* Manuals, that respectively set measurement guidelines for OECD Member countries in the areas of R&D and innovation.

Human resources devoted to biotechnology

Indicators on human resources devoted to biotechnology are among the most difficult to compile. While there can be indicators relating to human resources inputs to R&D and innovation coming from those type of collections, this omits any requirement for human resources involved in the application of biotechnology within industrial and other processes. These are potentially available from technology use surveys and hence it may be necessary to combine data from a range of collections if one is to develop an accurate measure of total human resources devoted to biotechnology. Of course taking data from different sources leads to potential problems with overlap and gaps between them.

Stocks of biotechnology human resources

Human resources qualified in biotechnology, but not necessarily in a scientific or biotechnology occupation, require data from different sources. Some countries have Population Censuses that are able to provide such data; these of course tend to be very infrequent data points. Other countries have population (or household) surveys that can also be used for such purposes but often the data from these is unavailable at that level of detail. In other countries there is data available from administrative records. The OECD and Eurostat have jointly developed a statistical manual (the Canberra Manual (OECD 95)) which aims to address this question for highly qualified people in general; the revision of this manual may provide an opportunity to include a demand for such data in the revision of that Manual.

Patents and citations

There seems to be a demand for patents and citations data in respect of biotechnology processes.There is a significant body of data that is available from national and international Patent Offices and these ought to be used to provide indicators. The OECD Patent Manual (94) provides guidelines on compiling and interpreting the data.

Venture capital

Venture capital is an important determinant of the biotechnology industry and business start-ups in biotechnology. There is very little official information available; however, there is a considerable body of statistics which are put together from private sources.

Biotechnology diffusion

This is a most important aspect of a framework for biotechnology statistics; there are examples of such surveys from Canada and France and shortly from New Zealand. Within such surveys it is possible to address many of the user requirements for statistics on biotechnology. However they are by nature one-off and quite expensive to conduct. Thus while such surveys are an integral part of an overall framework, they need to be supplemented by other options.

Production and trade in biotechnology products

The measurement of trade and local production in biotechnology products is a more difficult statistical issue. There are no readily-available lists of firms that undertake the production of biotechnology produced goods; clearly there are some industries that can be targeted for the measurement of relevant products and this might be an acceptable approach. International trade, however, is a much more difficult issue. International trade in products is generally measured via administrative records and these are unlikely to be suitable for use in identifying trade in biotechnologically produced goods, at least in the short to medium term.

Business start-ups

Business start-ups is an indicator that is frequently used, particularly to measure the growth of new emerging “industries”. It is however one which is very difficult to measure, as most countries have significant difficulty measuring business start-ups in general. Nevertheless it is an area which is of great importance from a political viewpoint and needs to be incorporated into an overall statistical framework.

Structural information about biotechnology firms

Much “political” debate goes on about the size of the biotechnology industry; but is there such an industry? Generally in standard industrial classifications businesses are classified to an industry on the basis of their outputs and their production processes. So, logically, there is no industry classification which specifically identifies biotechnology, as this a process. The outputs of a business are not split between whether they are biotechnologically produced, or otherwise.

Thus while it may not be possible to define a biotechnology industry in the normal way, there will be a demand for information about the overall size of the sector which is involved in biotechnology and this will need to be accommodated in the overall framework.

Conclusion

Work to date has shown that there is very little data on biotechnology available from national statistical sources, with the exception of Canada and to a lesser extent, France. While this severely limits the nature of analysis that can be undertaken, it does present a good opportunity for countries contemplating the collection of biotechnology statistics to benefit from the experience of these leading countries, which in turn should ensure a greater degree of international comparability. By sharing experiences on what works and does not, a solid set of data can be constructed internationally that can be used to analyse the various issues that will be associated with this technology. Even though statistical work is at an embryonic stage in individual countries, it is important that an international dimension be initiated now as well. This will avoid the situation where we now find ourselves in the area of indicators for the information society where 20 years after the invention of the PC we still do not internationally comparable indicators of ownership and use of PCs in households. While not a resource free proposition, if initiated soon, this work will be far less costly than if launched 20 years hence.

References

(1) System of National Accounts, 1993 – Eurostat, IMF, OECD, UN, World Bank.

(2) OECD/Eurostat, (1997), Proposed Guidelines for Collecting and Interpreting Technological Innovation Data – Oslo Manual, Paris/Luxembourg, OECD/Eurostat.

(3) OECD, (1993), Proposed Standard Practice for Surveys of Research and Development – The Frascati Manual, Paris, OECD.

(4) Australian Standard Research Classification (ASRC), 1998 – Australian Bureau of Statistics, Cat No 1297.0.

(5) OECD, (1994), Using Patent Data as Science and Technology Indicators – Patent Manual, Paris, OECD.

(6) OECD, (1995), The Measurement of Human Resources Devoted to S&T – Canberra Manual, OECD/GD(94)114, Paris, OECD.

ANNEXES


ELECTRONIC PUBLICATIONS AVAILABLE AT
www.statcan.ca

ANNEX 1: LIST OF RESPONSES TO QUESTIONNAIRE SORTED BY COUNTRY

The following is a summary of the results of the questionnaire distributed by the OECD in October 1999. We have included the definition of biotechnology used in the survey. Only when respondents made direct reference to the national biotechnology associations are those mentioned in this section.

AUSTRALIA

Australian Bureau of Statistics (ABS), by means of the R&D survey, collects some data on biotechnology. The data are for the Fields of Research: 060300, Industrial Biotechnology and Food Sciences and 080200, Genetics, Molecular Biology and Biotechnology. Data are collected for R&D expenditure and human resources in Business Enterprise, Higher Education, Private-Non-Profit and Government sectors.

ABS has done little on biotechnology to date. Neither the old (FOR) or new (RFCD) classifications clearly identify biotechnology. The latter goes further in that a separate group has been set up under Biological Sciences, although biotechnology is also covered in a number of other fields.

The Department of Industry, Science and Resources (ISR) has made some progress. They have set up a separate area, Biotechnology Australia, which has generated an Australian Biotechnology Directory and also an Australian Biotechnology Report. Both are available on their website http://biotech.isr.gov.au

The Directory was produced in association with the Australian Biotechnology Association (http://www.aba.asn.au).

The Australian Biotechnology Report was jointly produced by Ernst & Young and ISR and follows the style of reports produced by Ernst & Young overseas (e.g. for Canada).

Definition: “Biotechnology” means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. Biotechnology is simply the use of micro-organisms, and plant and animal cells, to produce materials such as food, medicine and chemicals that are useful to mankind.

CANADA

Statistics Canada collects a wide array of statistics on biotechnology by means of a biotechnology firm survey. Canada is developing a new survey to be released shortly.

Several variables are also collected at the provincial level. A list of variables currently covered by their survey can be provided on request.

Publications:

“Biotechnology Use by Canadian Industry – 1996”, Working Paper ST-98-05.

“Diffusion of Biotechnologies in Canada”, Research Paper No. 6.

“Canadian Biotechnology ’98; Success from Excellence”, BIOTECanada.

“Biotechnology Scientific Activities in Federal Government Departments – 1997-98”, Vol.22, No.4.

“Biotechnology R&D in Canadian Industry – 1995”, Vol.21, No.11.

“Canadian Biotechnology Statistics”, CBS Theme 9.

Sites:

http://www.statcan.ca/english/research/scilist.htm.
French version: http://www.statcan.ca:80/francais/concepts/science_f.htm.
http://strategis.ic.gc.ca.

Definition: Rather than defining biotechnology Canada has established a list of 22 biotechnologies:

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

DENMARK

As of 1991, the Danish Institute for Studies in Research and Research Policy (http://www.afsk.au.dk) started collecting biotechnology data from the public and private sectors as a part of the national R&D survey. The variables covered include R&D units, R&D personnel, R&D expenditure and R&D cost. Data available for: 1991-97.

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

FINLAND

Statistics Finland does not collect data on biotechnology, however the Academy of Finland has produced a background document on the “Evaluation of Molecular Biology and Biotechnology Research” (1996).

Finnish Bio-industries (http://www.finbio.net) produces an “Index of Biotechnology Companies, Organisations and Science Centres in Finland” (1999).

FRANCE

MENRT (Ministère de l’éducation nationale, de la recherche et de la technologie — Bureau des études statistiques sur la recherche) — does not collect biotechnology statistics as a part of its R&D survey but intend to do so in future surveys. They have developed a biotechnology firm survey 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.

Data collection for this survey began in 1999. France counts approximately 1000 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, and an area was set up on the web so that the questionnaire could be filled in electronically.

Site:

http://www.education.gouv.fr/technologie/biotec/somm.htm.

Definition: 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 gènes	Pharmacogénomique
Bioinformatique	Galénique	Protéomique
Bioprocess	Hormones et facteurs de croissance	Purification/séparation
Biopuces	Hybridation, fusion cellulaire	Séquençage
Bio-réacteur	Ingénierie des glucides	Synthèse des molécules
Chimie chirale	Ingénierie des lipides	Système de délivrance (vecteurs)
Chimie combinatoire	Ingénierie des protéines	Traitements des produits et substituts sanguins
Contrôle des procédés	Ingénierie des tissus	Transgénèse
Criblage de molécules haut débit	Instrumentation	Autres : préciser :
Culture des tissus ou des cellules	Isolation de peptides et synthèse	

JAPAN

In 1995, the Statistics Bureau, Management and Co-ordination Agency of the Government of Japan incor- porated an R&D Survey on Life Sciences. This survey includes questions on the number of persons engaged in gene recombination (rDNA) R&D as well as expenditure.

The Japan Bio-industry Association (JBA) has a survey on the biotech industry. This survey covers the number of companies, revenues, employees and R&D. (http://www.jba.or.jp)

The JAPIO (Japan Patent Information Organisation) database PATOLIS also provides data on biotechnology Patent applications (ICP categories: AO1G, AO1H, A61K, C12N, C12P, and C12Q; aggregate of patents and petty patents). (http://www.european-patent-office.org/espacenet/help/paj/data1.htm).

Nikkei Biotechnology (http://biotech.nikkeibp.co.jp) published a document that covers biotechnology developments in Japan. An English version can be found at http://www.dfait-maeci.gc.ca/ni-ka/scitech/biotech-e.asp.

Definition: The definition of a company using biotechnology in this survey is wide, because the target of the survey was not limited to the products employing modern biotechnology, but also extended into the areas of brewing and fermented products from the old biotechnology area.

NETHERLANDS

An R&D survey is sent out by Central Bureau of Statistics (CBS) to enterprises and research institutes. Every other year the break down of R&D-full-time-equivalents into technology fields is requested; one of them being biotechnology.

NEW ZEALAND

The Ministry of Research, Science and Technology is in the process of developing a questionnaire to be sent out in May-June 2000.

MEXICO

Dr. Rodolfo Quintero-Ramirez, from the Institute of Engineering at the National University of Mexico, published a paper called “Biotechnology in Mexico: a retrospective reflection 1982-1997” in a Journal entitled: “Biotecnologia” Vol. 3, No. 3, p. 133-172, September 1998. This document is in Spanish. The method used to obtain the data included in the paper were visits to the research groups and consultations of web pages of each research centre.

SPAIN

CINDOC-CSIC (Consejo Superior de Investigaciones Cientificas Centro de Informacion y Documentacion CIENTIFICA) has published a catalogue of “Spanish Research groups and enterprises working in Biotechnology 1997.” It was published as a book and a CD-ROM and includes information on the technologies used by 766 groups and approximately 150 enterprises.

SWEDEN

NUTEK (Swedish National Board for Industrial and Technical Development) is working on a report using bibliometric and patent data in order to analyse the Swedish Biotechnology cluster.

UNITED STATES

Biotechnology data is not available from official statistics. The National Science Foundation (NSF) is not able to document industry’s biotechnology activities for a variety of reasons, the most important being that biotechnology is not a separate industry code in its Standard Industrial Classification. This year the Census (the collection agent for the source survey of industrial R&D expenditure data) is going to conduct a special study to determine where the biotechnology companies are classified. Many are classified in the pharmaceuticals industry (283), some are in Research, development and testing services (SIC 873) and some are elsewhere. Unfortunately, the “old” industrial classification codes as well as the new NAICs industrial classification system, to be implemented beginning with statistics for 1999, also do not have any discrete industry listings for biotechnology firms—another reason for undertaking the special study with the Census.

Patent data

U.S. Patent and Trademark Office (http://www.uspto.gov) periodically identifies patent classes associated with biotechnologies and reports patent activity by U.S. and foreign resident inventors. NSF/SRS did fund a study of international patent activity (performed by Mogee Research & Analysis Associates) in several technology areas using the Derwent World Patent Index Database. Biotechnology was one of the areas examined with patent activity in genetic engineering used as a representative of biotechnology. Those data were presented in *Science & Engineering Indicators—1998* and in a separate issue brief released by this Division.

Trade data

The U.S. Census Bureau (http://www.census.gov/foreign-trade/www/sec2.html#hs) reports on U.S. trade in biotechnology in its database on Advanced Technology Products. Those data have been reported in Science & Engineering Indicators and in other publications.

Advanced Technology Products (ATP).

Approximately 500 of the Harmonised Tariff Schedule of the United States Annotated for Statistical Reporting Purposes (HTSUSA) and Schedule B commodity classification codes used in reporting U.S. imports and exports are identified as "advanced technology" codes that must meet the following criteria:

The code contains products whose technology is from a recognised high technology field (e.g., biotechnology).

- These products represent leading edge technology in that field.
- Such products constitute a significant part of all items covered in the selected classification code.

This product and commodity-based measure of advanced technology differs from broader SIC industry-based measures which include all commodities produced by a particular industry group, regardless of the level of technology embodied in the commodities.

HTSUSA is the U.S. import version of the Harmonised System.

Non-government biotechnology data collection

Biotechnology R&D data available from the Biotechnology Industry Organisation (a trade association for biotechnology firms). http://www.bio.org/welcome.html.

Biotechnology firm data (counts and research focus) from the Institute for Biotechnology Information (Research Triangle Park database). http://www.biotechinfo.com/.

Venture capital funds: Venture Economics, Inc, Newark New Jersey, a private data collector that compiles data on the U.S. venture capital industry. It classifies much of those data by technology areas, one of which is biotechnology. NSF/SRS routinely purchases data from this company and reports those data in a variety of publications.

Newly formed companies already operating by technology areas: CorpTech Directory of Technology Companies, located in Woburn, Mass., maintains a somewhat incomplete database of new technology companies operating in the U.S. Biotechnology is one of the technology areas listed in its classification system.

EUROPEAN COMMISSION

The European Commission has published two volumes of country studies.

"The volumes present an inventory of publicly-funded biotechnology R&D stimulation programmes in 17 European countries. The work was limited to public research, including charities, hence ignoring research carried out at universities and private laboratories. Aspects of technology transfer between the public and private sector, however, are presented briefly.

It is understood that such a complex work (by matter as well as by scope) can never be perfect. The information given is as good as the informants. The national presentation, despite utmost efforts of structuring and harmonising, does not really allow comparisons at international level".

(European Commission, Inventory of public biotechnology R&D programmes in Europe: Volume 1 Analytical report, 1999 EUR 18886/1 EN)

Each national file is structured as follows:

- Background: setting the national scene.
- The national system for biotech funding: policy and instruments.
- National competencies and priorities.
- Public and private biotech infrastructure.
- References and people interviewed.

These national files are an invaluable source of information and could prove useful in the early stages of this project.

Publications:

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

"Inventory of Public Biotechnology R&D Programmes in Europe: National Reports Volume 1. - 1999".

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

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

Definition: "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).


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ANNEX 2: NON-EXHAUSTIVE LIST OF EXTERNAL SITES AND PUBLICATIONS

The following section provides an overview of the types of sites that are accessible to the wider public as well as reports prepared by consulting firms. This list is by no means complete or sorted in any particular order. The descriptive paragraph that follows each website reference has been drawn directly from the respective sites.

http://www.ey.com/

Ernst & Young consulting has produced numerous reports that track developments in the biotechnology field. These publications include statistical data. They have produced reports for Europe, the U.S., Germany and Belgium (forthcoming - in conjunction with the Belgian Biotechnology Association) as a "marketing leadership initiative to demonstrate our commitment to the sector and our knowledge of the sector." The US report is in its 14th year of publication and the European in its 7th year.

Publications:

Ernst &Young LLP, *Bridging the Gap*, 1999 (USA).

Ernst &Young, Australian Biotechnology Report 1999, 1999.

Ernst &Young LLP, *European Life Sciences*, 1999.

Ernst &Young LLP, *New directions '98*, 1998 (USA).

Ernst &Young, Germany's Biotechnology Takes Off in 1998, 1998.

Ernst &Young LLP, *European Life Sciences*, 1998.

Ernst &Young LLP, Canadian Biotech '97, Coming of Age, 1997.

Definition: "The Ernst & Young definition of so-called "Entrepreneurial Life Sciences Companies" (ELISCO), that is commercial companies whose main business purpose is to research, develop and sell products, technologies and services on the basis of modern biotechnology. The fields of application lie in the field of healthcare (therapeutics and diagnostics), agriculture, food, biotechnology fine chemicals and basic goods production as well as environmental protection. These sectors are generally referred to collectively as the "Life Sciences Industry."

Modern biotechnology means all innovative methods, processes or products which mainly involve the use of living organisms or their cellular and sub-cellular components and which use research results in the field of biochemistry, molecular biology, immunology, virology, microbiology, cell biology or environmental technology and process engineering within the framework of a causative interpretation".

(E&Y, Germany's Biotechnology Takes Off in 1998, 1998).

http://www.arthurandersen.com/

Arthur Andersen produced a report on the United Kingdom Biotechnology Industry in 1997.

Publications:

(Arthur Andersen, UK Biotech '97 - Making the Right Moves, 1997).

Definition: Biotechnology is defined as "those companies whose primary commercial activity depends on the application of biological organisms, systems or processes".

(Arthur Andersen, UK Biotech '97 - Making the Right Moves, 1997).

h*ttp://www.biotechknowledge.com/*

The Knowledge Center, sponsored by Monsanto. This site is an evolving collection of news items, technical reports, fact sheets, speeches and other documents. The site assembles material representing many varying points of view. The principal aim is to promote a deeper understanding of food biotechnology and other life sciences and the many issues associated with them.

http://www.nuffield.com/bioethics/

New developments in medicine and biology raise important ethical issues. The Nuffield Council on Bioethics is required, in its terms of reference, to consider these issues.

The Nuffield Council on Bioethics is an independent body established by the Trustees of the Nuffield Foundation in 1991. The Council is jointly funded by the Nuffield Foundation, The Wellcome Trust and the Medical Research Council.

http://www.biocompass.com/

Biotechnology Transfer Services (BTS), established in 1986, is a US-based management consulting firm providing global biotechnology business development services, with historical emphasis in Asia-Pacific and the US. Recent expansion now provides for coverage of Europe.

http://www.biocentury.com/

Newsletters, conferences and research services, analysis, interpretation and commentary relating to biotechnology industry development, corporate strategy and shareholder value. This site also provides a page of biotechnology links to industry organisations, government agencies, press release sources, financial resources, newsgroups and scientific journals.

http://www.oecd.org/ehs/biolinks.htm#National Biotechnology Web Sites

This site includes a list of links to Other Biotechnology or Biosafety Resources on the Web.

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

Canadian Department of Foreign Affairs and International Trade has documents on biotechnology in different countries: 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.

ANNEX 3: NON-EXHAUSTIVE LIST OF SINGLE BIOTECH DEFINITIONS

AUSTRALIA

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. Biotechnology is simply the use of micro-organisms, and plant and animal cells, to produce materials such as food, medicine, and chemicals that are useful to mankind.

CANADA

Biotechnology has been defined [Agriculture and Agri-Food Canada. Regulation of Agricultural Products of Biotechnology, August 31, 1993.] as "the application of science and engineering to the direct or indirect use of living organisms, or parts or products of living organisms, in their natural or modified forms".

DENMARK

"No definition is given in the national R&D questionnaire. The reason is that the whole question relates to topics on the R&D agenda at the specific time of the survey, and at the given time when it is included in the R&D questionnaire "everyone" in the scientific field knows the issue from the debate and the programme announcements."

FRANCE

Les biotechnologies — technologies pour et par le vivant — visent à améliorer la santé de l'homme et son environnement naturel et nutritionnel.

Biotechnologies — technologies for and by living organisms — aim to improve well being of mankind as well as his nutritional and natural environment.

JAPAN

The definition of a company using biotechnology in this survey is wide, because the target of the survey was not limited to the products employing modern biotechnology, but also extended into the areas of brewing and fermented products from the old biotechnology area.

NETHERLANDS

The science of the production processes based on the action of micro-organisms and their active components, and of production processes involving the use of cells and tissues from higher organisms — A Dutch Perspective, 1981.

NEW ZEALAND

New Zealand Biotechnology Association defines modern biotechnology 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."

UNITED KINGDOM

UK Dept of industry — Biotechnology is the application and exploitation of biological organisms, systems and processes.

UNITED STATES

"Any technique that uses living organisms, or substances from those organisms, to make or modify a product or process, to improve plants or animals, or to develop micro-organisms for specific uses". The collection of industrial processes that involve the use of biological systems. The use of living organisms or their components in industrial processes — OTA Report 1981.

Perhaps unique among industries, biotechnology is not defined by its products but by the technologies used to make those products. Biotechnology refers to a set of enabling technologies used by a broad array of companies in their research, development, and manufacturing activities. To date, these technologies have been used primarily by the pharmaceutical industry, but they are being used increasingly by a variety of other industries, such as agriculture, mining, and waste treatment. Various U.S. government publications have defined biotechnology as a set of techniques that use organisms or their cellular, subcellular, or molecular components, to make products or modify plants, animals, and micro-organisms to carry desired traits. This broad definition includes methods of treating disease developed from recent research in molecular biology and other fields, as well as the centuries-old practices of animal and plant breeding and the use of micro-organisms to make leavened bread and fermented beverages. Advances in molecular biology over the past 25 years have led to the development of genetic engineering, monoclonal antibody technologies, DNA amplification, protein engineering, tissue engineering, and other methodologies with applications in the medical arena. These new techniques have enabled researchers to modify the genetic and biochemical makeup of organisms with far greater precision and speed.

(U.S. Department of Commerce, Office of Technology Policy, *Meeting the Challenge: U.S. Industry Faces the 21st Century - The U.S. Biotechnology Industry*, 1997).

OECD

"Biotechnology is the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services." (OECD, Biotechnology: International Trends and Perspectives, Paris, 1982).

EC

"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).

ERNST & YOUNG

"The Ernst & Young definition of so-called "Entrepreneurial Life Sciences Companies" (ELISCO), that is commercial companies whose main business purpose is to research, develop and sell products, technologies and services on the basis of modern biotechnology. The fields of application lie in the field of healthcare (therapeutics and diagnostics), agriculture, food, biotechnology fine chemicals and basic goods production

as well as environmental protection. These sectors are generally referred to collectively as the "Life Sciences Industry."

Modern biotechnology means all innovative methods, processes or products which mainly involve the use of living organisms or their cellular and sub-cellular components and which use research results in the field of biochemistry, molecular biology, immunology, virology, microbiology, cell biology or environmental technology and process engineering within the framework of a causative interpretation."

(**E&Y, Germany's Biotechnology Takes Off in 1998, 1998).**

ARTHUR ANDERSEN

Biotechnology is defined as "those companies whose primary commercial activity depends on the application of biological organisms, systems or processes."

(Arthur Andersen, UK Biotech '97 — Making the Right Moves, 1997).


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ANNEX 4: LIST OF BIOTECHNOLOGIES USED IN NATIONAL SURVEYS

CANADA

List of 17 biotechnologies used for the Biotechnology Firm Survey - 1997.
(The Canadian Industry Survey - 1996 - had a list of 22 biotechnologies).

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
- Diagnostic Tests / Antibodies
- Peptide / Protein Sequencing or synthesis
- Cell Receptors / Cell Signalling / Pheroemones / 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 Products Chemistry
- Others (Please specify)

FRANCE

In its biotechnology firm survey 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 gènes	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 chirale	Ingéniérie des lipides	Système de délivrance (vecteurs)
Chimie combinatoire	Ingéniérie des protéines	Traitements des produits et substituts sanguins
Contrôle des procédés	Ingéniérie des tissus	Transgénèse
Criblage de molécules haut débit	Instrumentation	Autres : préciser :
Culture des tissus ou des cellules	Isolation de peptides et synthèse	

NEW ZEALAND

In its biotechnology firm survey New Zealand has a single definition as well as a list of 55 biotechnology processes.

DNA: BASED:TECHNOLOGY USING CHEMISTRY OF DNA AS A MAJOR COMPONENT

1. Genetic Engineering / Recombinant DNA: The manipulation of an organism's genetic material by introducing or eliminating specific genetic changes through modern molecular biology techniques.
2. Gene Probes: A section of DNA or RNA of known structure or function which is marked with a radioactive isotope, dye or enzyme that can be used to detect the presence of a similar sequence from any biological material.
3. Bio-informatics: Computer-based analysis of biological information (bio-info), especially genomics and molecular modelling (*e.g.* DNA/RNA/ protein sequencing and databases for genes of humans, plants, animals and micro-organisms).
4. Pharmacogenetics: The study of the genetics of drug production, action or assimilation.
5. Genomics: The use and organisation of information of biological interest, including the construction and analysis of genes that may be used to search for new genes of interest, matching existing genes etc.
6. DNA Sequencing: A method to determine the order of nucleotides on a gene or DNA fragment.
7. DNA Synthesis: Design and synthesis of a DNA molecule from existing information of its constituent bases.
8. DNA Amplification: Process of increasing the number of copies of a particular gene of chromosomal sequence.

9. Gene therapy: Replacement of a defective gene in an organism suffering from a genetic defect.
10. Rational drug design: Analysis of the structures of active sites of enzymes and receptors in order to design pharmocologically active synthetic molecules.
11. Other (Please specify).

BIOCHEMISTRY / IMMUNOCHEMISTRY BASED: TECHNOLOGY WHICH UTILISES IMMUNOCHEMISTRY / ANTIBODIES OR ENZYMES AS A MAJOR COMPONENT

12. Vaccines: The agent containing antigens produced from killed, attenuated or live pathogenic micro-organisms or their genetic material used to stimulate the immune system to protect the host.
13. Immune Stimulants: Compounds that induce the immune system to produce antibodies or antibody containing lymphocytes.
14. Combinatorial Chemistry: An approach to chemical synthesis that enables the creation of large numbers of organic compounds by putting chemical building blocks together in every possible combination. It is used to synthesise novel compounds, which are screened, or tested, against biological targets as part of the drug discovery process.
15. Drug Design and Delivery: Development of drugs where the raw materials and/or processes involve the use of biotechnology.
16. Diagnostic Tests: A test used to determine the source of a problem or a method of determining the nature of a disease by analysing the symptoms.
17. Peptide / Protein Synthesis: Procedure to link two or more amino acids joined by a linkage called a peptide bond.
18. Peptide / Protein Sequencing: The process of determining the sequence of a polypeptide or cluster of polypeptides, or the process of creating a new substance from precursor molecules.
19. Cell Receptors: Functional proteinaceous structures found in the membrane (surface) of cells that tightly bind specific molecules (organic, protein or viruses).
20. Cell Signalling: The mechanism used by cells to induce or trigger events at remote sites within cells.
21. Bio-sensing: Use of biological molecules (e.g. enzymes, antibodies) in conjunction with a transducer to low level detection of substances such as sugars and proteins in body fluids, pollutants in water, etc.
22. Pheromones: Compounds emitted by insects and spread through the air for the purpose of attracting the opposite sex.
23. Three Dimensional Molecular Modelling: Description of the characteristics of molecules through a 3D spatial representation.
24. Structural Biology: The study of the three dimensional structures of biological molecules (such as proteins) and their mutual interactions as a means of understanding the functions of these molecules within the cell.
25. Antigens: A substance that stimulates the production of specific neutralising antibodies in an immune response. Any chemical substance, usually protein that interacts with an antibody.
26. Monoclonal Antibodies: A monoclonal antibody is a highly specific antibody which is derived from a line of specialised cells and which recognises only one specific complimentary antigen.
27. Antibodies: Proteins that circulate in the blood stream and bind to foreign invading substances (antigens e.g. bacteria, toxins, certain viruses) with a great deal of specificity.
28. Microbiology / Microbial Ecology: Study of organisms that are too small to be seen with the naked eye.
29. Biomaterials: Any biologically derived material which is used for its material properties rather than its biological properties.
30. Other (Please specify)

ENVIRONMENTAL BIOTECHNOLOGIES: BIOTECHNOLOGIES USED FOR POLLUTION CONTROL

31. Bioaugmentation: The process of increasing the efficiency of the naturally occurring microbial population to concentrate or accumulate specific compounds. This is usually achieved by adding nutrients, oxygen or water.
32. Bio-reactors: Enclosed containers in which micro-organisms are maintained under controlled conditions for the purpose of creating or destroying specific compounds.
33. Biological Gas Cleaning: The use of micro-organisms to breakdown or degrade hazardous substances in a gas stream into less hazardous or non-toxic substances.
34. Bio-remediation: The use of naturally occurring or genetically modified micro-organisms to breakdown or degrade hazardous substances into less hazardous or non-toxic substances.
35. Phytoremediation: The use of plants to treat or clean environmental pollution.
36. Other (Please specify).

BIOPROCESSING BASED: PROCESSING OF ANY NATURAL MATERIAL OF BIOLOGICAL ORIGIN

37. Cell Culture: A population of cells grown for microbiological testing, cell culture development or in fermenters to study their biology or to manufacture products.
38. Tissue Culture: A technique for growing cells from multi-cellular organisms in a artificial medium.
39. Embryo Culture: A technique for growing embryos from multi-embryo organisms in an artificial medium.
40. Cell Manipulation: Ability to grow and modify a range of cell types under laboratory conditions.
41. Tissue Manipulation: Ability to grow and modify a range of tissue types under laboratory conditions.
42. Embryo Manipulation: Ability to grow and modify a range of embryo types under laboratory conditions.
43. Fermentation: Micro-organic process in which the metabolism of sugars for energy is accompanied by the formation of alcohol or lactic acid.
44. Bioprocessing: Production stages that include fermentation, recovery and purification.
45. Biotransformation: Conversion of one chemical or material into another using a biological catalyst.
46. Bio-leaching: Use of micro-organisms to leach metals from ore.
47. Bio-pulping: The use of enzymes to degrade wood structures to produce pulp for papermaking purposes.
48. Bio-bleaching: The use of enzymes to bleach paper fibre.
49. Bio-desulphurisation: The removal of organic or inorganic sulphur from coal by bacterial or soil micro-organisms.
50. Bio-pesticide Manufacturing: Biological pest control through the use of naturally occuring microbes or bacteria.
51. Extraction / Concentration /Purification / Separation: The retrieval of a compound of interest from a raw material.
52. Biofiltration: The treatment of sewage or industrial wastewaters using active biomass growing on a solid support.
53. Bioindicators: The use of organisms to indicate the status of an environment.
54. Classical / traditional Breeding: Genetic improvement of animals or plants by breeding selected individuals.
55. Natural Products Chemistry: The study of a biological material or a biologically-derived material using analytic methods, normally being the isolation and identification of the novel chemicals within a biological material.
56. Microbio-inoculants: Naturally occurring bacterial inoculates used to promote plant growth.

57. Bio Sensing: Process that uses biological molecules e.g. enzymes or antibodies in conjunction with a transducer to low level detection of substances such as sugars and proteins in bodily fluids, pollutants in water, etc.
58. Somatic Embryo-genesis: Propagation of genetically desirable plant and tree lineages by tissue culture methods.
59. Other (Please specify).


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88-204-XIB Federal Scientific Activities, 1999-2000e (annual)
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Volume 24

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No. 3 Industrial Research and Development, 1996 to 2000

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No. 5 Federal Government Expenditures on Scientific Activities, 2000-2001e

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ST-98-09 Federal Government Expenditures and Personnel on Activities in the Natural and Social Sciences, 1989-90 to 1998-99e, September 1998

ST-98-10 Knowledge Flows in Canada as Measured by Bibliometrics, October 1998

ST-98-11 Estimates of Canadian Research and Development Expenditures (GERD),Canada, 1987 to 1998e and by Province 1987 to 1996, October 1998

ST-98-12 Estimation of Research and Development Expenditures in the Higher Education Sector, 1996-97, November 1998

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