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GUIDELINES FOR A HARMONISED STATISTICAL APPROACH TO BIOTECHNOLOGY RESEARCH AND DEVELOPMENT IN THE GOVERNMENT AND HIGHER EDUCATION SECTORS

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FOREWORD

This document presents the final *Guidelines for a Harmonised Statistical Approach to Biotechnology Research and Development in the Government and Higher Education Sectors*.

The aim of these guidelines is to propose a harmonised approach for the collection and analysis of biotechnology research and development (R&D) statistics in the government and higher education sectors. To simplify, this document calls the government and higher education sectors the "public sector" when they are treated together. In some countries, this definition of the public sector may differ from that of the official definition in the System of National Accounts.

Guidelines for collecting statistics on “public” biotechnology R&D funding were beyond the scope of the 2005 version of the *Framework for Biotechnology Statistics*. However, the collection of data on public biotechnology R&D expenditure and funding is seen as highly relevant to policy decisions and the guidelines on how to undertake this represent an extension of the development of statistical standards.

In 2005, the Working Party of National Experts on Science and Technology Indicators (NESTI) decided to set up a group to work on elaborating guidelines for collecting statistics on public biotechnology R&D expenditure and funding. This project was undertaken by delegates to the *Ad Hoc* Meeting on Biotechnology Statistics.

During the process, several drafts were discussed by NESTI. At the 2008 *Ad Hoc* Biotechnology Statistics meeting, it was decided to finalise the guidelines for collecting statistics on public biotechnology R&D expenditure and funding. This meant reviewing the proposed guidelines and model questionnaire, to ensure consistency with the *Frascati Manual*.

An earlier version of this document was presented to the NESTI in June 2009. The report was revised and amended to reflect comments and new information received by delegates and experts.

At the request of the NESTI body, the Committee for Scientific and Technological Policy (CSTP) was invited to declassify the document under the written procedure. This was completed in November 2009.

This document is published under the responsibility of the Secretary-General of the OECD.

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GUIDELINES FOR A HARMONISED STATISTICAL APPROACH TO BIOTECHNOLOGY RESEARCH AND DEVELOPMENT IN THE GOVERNMENT AND HIGHER EDUCATION SECTORS

Over the last fifteen years, biotechnology has been considered by policy makers as one of the main fields of innovation. It has thus become a major target for research and innovation policy in many of the world's developed and developing countries. However, research and innovation policy is very dependent on the existence of reliable and internationally comparable data in order to make informed decisions on how best to promote biotechnology development.

The aim of these guidelines is to propose a harmonised approach for the collection and analysis of biotechnology research and development (R&D) statistics in the government and higher education sectors. To simplify, this document calls the government and higher education sectors the "public sector" when they are treated together. In some countries, this definition of the public sector may differ from that of the official definition in the System of National Accounts.

Biotechnology R&D in the public sector is called "public biotechnology R&D". These guidelines cover both the performance of biotechnology R&D within the public sector and the public funding of biotechnology R&D. The definitions and recommendations presented below are based on the *Frascati Manual* (FM) (OECD, 2002) and *A Framework for Biotechnology Statistics* (OECD, 2005).

1. DEFINITIONS

1.1. Definition of "research and development"

The definition of "research and development" (R&D) to be used in the framework of surveys and statistics on public biotechnology R&D is that of the *Frascati Manuel*:

> *"*Research and experimental development (R&D) comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications*".*
> *Source:* OECD, *Frascati Manual,* 2002, p. 30.

1.2. Definition of biotechnology R&D

The definition of "biotechnology R&D" to be used in the framework of surveys and statistics on public biotechnology R&D is that of the *Framework for Biotechnology Statistics*:

> "Biotechnology research and experimental development (R&D) – defined as R&D into biotechnology techniques, biotechnology products or biotechnology processes, in accordance with both the biotechnology definitions presented above and the *Frascati Manuel* for measurement of R&D (OECD, 2002)".
> *Source:* OECD, *A Framework for Biotechnology Statistics,* 2005, p. 10.

1.3. Definition of biotechnology

The definition of biotechnology to be used in the framework of surveys and statistics on public biotechnology R&D is that of the *Framework for Biotechnology Statistics*:

Single definition

The provisional single definition of biotechnology is deliberately broad. It encompasses all modern biotechnology but also many traditional and borderline activities. For this reason, the single definition should always be accompanied by the list-based definition which operationalises the definition for statistical purposes. The single definition is as follows:

> *"*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*".*

Source: OECD, *A Framework for Biotechnology Statistics,* 2005, p. 9.

List-based definition

The biotechnology techniques listed in Box 1 function as an interpretative guideline to the single definition. This list is indicative rather than exhaustive and is expected to change over time as data collection and biotechnology activities evolve.

Box 1. The list-based definition of biotechnology techniques

DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.

Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors.

Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.

Gene and RNA vectors: Gene therapy, viral vectors.

Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.

Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.

Source: OECD, *A Framework for Biotechnology Statistics,* 2005, p. 9.

2. INSTITUTIONAL CLASSIFICATION

Public R&D encompasses all R&D carried out or funded by the public sector. The public sector is defined on the basis of the definitions of institutional sectors published in the FM. The public sector encompasses the government sector and the higher education sector.

The survey should respect the borderlines between sectors as defined in the FM, so as to obtain the public sector's total biotechnology R&D as well as the government and higher education sectors separate biotechnology R&D.

2.1. Government sector

"The government sector is composed of:

- All departments, offices and other bodies which furnish, but normally do not sell to the community, those common services, other than higher education, which cannot otherwise be conveniently and economically provided, as well as those that administer the state and the economic and social policy of the community. (Public enterprises are included in the business enterprise sector.)

- Non-profit institution (NPIs) controlled and mainly financed by government, but not administered by the higher education sector."

Source: OECD, *Frascati Manual,* 2002, p. 62.

2.2. Higher education sector

"The higher education sector is composed of*:*

- All universities, colleges of technology and other institutions of post-secondary education, whatever their source of finance or legal status.

- It also includes all research institutes, experimental stations and clinics operating under the direct control of or administered by or associated with higher education institutions."

Source: OECD, *Frascati Manual,* 2002, p. 68.

2.3. Statistical unit

The public-sector statistical unit corresponds to this sector's legal entities.
The government sector's legal entities are classified into three categories, according to the level of government involved:

- central and federal government units
- provincial and state government units
- local and municipal government units.

The government and higher education sectors' statistical units are, for example:

- NPIs controlled and mainly financed by government
- institutions of higher education
- research institutes or centres
- clinics, health centres or university hospitals.

…
Source: OECD, *Frascati Manual,* 2002, p. 64.

The units to be surveyed in a public-sector biotechnology R&D survey are the units covered in the country's measurement or survey of R&D in the government and higher education sector. This harmonisation of the target population allows for comparisons by sector and with other R&D data collected during the R&D survey of the same sector. The government and higher education sectors comprise the NPIs and research institutions which are controlled and mainly financed by government. Private NPIs are not part of the public sector. They are defined as a separate sector in the FM.

The private units of the higher education sector, such as private universities, are included if they are officially recognised by the state. The higher education sector is defined in accordance with its function.

2.4. R&D performance units or funding units?

Public-sector statistical units may have biotechnology R&D expenditure which is used either within the unit (intramural) or outside it (extramural). Consequently, these units can be:

- agencies that perform biotechnology R&D (in this case their intramural R&D expenditure is recorded);
- agencies that finance other institutions active in biotechnology R&D (this funding is recorded in their extramural R&D expenditure);
- agencies that both perform and fund R&D and therefore have both intramural and extramural expenditures on R&D.

The questionnaire should be addressed to all the units that are part of the government sector and all units that are part of the higher education sector (including the private units of the higher education sector). It is not necessary to know in advance whether the unit performs or funds R&D. The questionnaire should make it possible to record intramural and extramural expenditures separately and therefore to provide information on this topic. Presented separately, each of these totals provides important information:

- The sum of intramural R&D expenditures corresponding to the total expenditures incurred by the public sector to perform biotechnology R&D in its own institutions.
- The sum of extramural R&D expenditures corresponding to the public sector's total funding of biotechnology R&D.

However, at the national level, intramural and extramural expenditures cannot be summed because of the risk of double counting.

3. INTRAMURAL BIOTECHNOLOGY R&D EXPENDITURE

Public intramural biotechnology R&D expenditure is all biotechnology R&D performed by a public-sector unit on its own premises, regardless of its source of funds.

At the national level, the total of public intramural biotechnology R&D expenditure corresponds to all R&D expenditures incurred by the public sector as a performer of biotechnology R&D.

Intramural biotechnology R&D expenditure encompasses the labour costs of R&D personnel working for biotechnology R&D projects, other current costs for biotechnology R&D (rent, energy, various equipment, etc.) and capital expenditure incurred for the purchase of fixed assets used in biotechnology R&D projects.

This intramural R&D expenditure can be broken down in different ways. But all these ways of disaggregating R&D expenditure are not necessarily required for biotechnology R&D expenditure.

3.1. By expenditure type

- Labour costs of R&D personnel
- Other current costs
- Capital expenditures

Source: OECD, *Frascati Manual,* 2002, p. 108-112.

3.2. By type of R&D

- Basic research
- Applied research
- Experimental development

Source: OECD, *Frascati Manual,* 2002, p. 77-79.

3.3. By socio-economic objective

NABS 2007 chapters

- 1. Exploration and exploitation of the Earth
- 2. Environment
- 3. Exploration and exploitation of space
- 4. Transport, telecommunication and other infrastructures
- 5. Energy
- 6. Industrial production and technology
- 7. Health
- 8. Agriculture
- 9. Education
- 10. Culture, recreation, religion and mass media
- 11. Political and social systems, structures and processes
- 12. General advancement of knowledge: R&D financed from General University Funds (GUF)
- 13. General advancement of knowledge: R&D financed from other sources than GUF
- 14. Defence

Source: OECD, *Frascati Manual,* 2002, p. 86.
Source: EUROSTAT, *Nomenclature for the Analysis and Comparison of Scientific Programmes and Budgets (NABS),* 2007.

3.4. By field of science and technology

- Natural sciences
- Engineering and technology
- Medical and health sciences
- Agricultural sciences
- Social sciences
- Humanities

Source: OECD, DSTI/EAS/STP/NESTI(2006)19/FINAL, p. 12.

3.5. By field of biotechnology application

- Human health (with rDNA technology)
- Human health (without rDNA technology)
- Veterinary health
- Agriculture (new varieties of genetically modified (GM) products)
- Agriculture (new varieties of non-genetically modified (GM) products)
- Food and beverages processing
- Natural resources
- Environment
- Industrial processing
- Bioinformatics
- Non-specific applications
- Other

Source: OECD, *A Framework for Biotechnology Statistics,* 2005, p. 37 (revised).

4. FUNDING OF INTRAMURAL BIOTECHNOLOGY R&D

There are three main channels of funding for public intramural biotechnology R&D expenditure: on the one hand, the institution's own funds and, on the other, two major funding instruments – R&D contracts and R&D grants.

4.1. The public-sector units' own funds

Government-sector units' own funds are obtained from various taxes as well as sums that may have been obtained from the sale of services. In the higher education sector, own funds are obtained from student fees and possibly from the sale of services (such as continuing education).

4.2. Biotechnology R&D contracts awarded to the public sector

The public-sector unit is entrusted with biotechnology R&D contracts to perform biotechnology R&D for remuneration. The contracts are usually governed by private law. The contract awarder has a direct interest in using the results of the R&D to further its own activities; it can also supervise and monitor the progress of the research.

4.3. Biotechnology R&D grants awarded to the public sector

Biotechnology R&D grants are financial resources given as non-recoverable grants to a public-sector unit to encourage its biotechnology R&D activities. The grant awarder does not have a direct interest in the results of the R&D. It allocates and decides on grants. The use of the financial resources made available is by and large determined by the recipient. As a general rule, the provider of funds has little influence on the outcome of the R&D project. All basic funding from the state is considered as grants.

In the government sector, the two funding types, contracts and grants, will generally not need to be recorded separately, because government-sector units rarely receive grants. But the distinction is worth making for the higher education sector.

Biotechnology R&D contracts and grants can be broken down into the following sources of funds:

4.4. By funding type and source of funds

Public-sector units' own funds

R&D contracts awarded to public-sector units by:

Funds from institutions within the country:

- private enterprises
- government-sector institutions:
  - central and federal government units
  - provincial and state government units
  - local and municipal government units
  - public general university funds
- higher education sector institutions
- private non-profit institutions.

Funds from institutions abroad:

- private enterprises
- government-sector institutions
- higher education sector institutions
- private non-profit institutions
- European Union (*e.g.* Framework Programmes)
- international research organisations (*e.g.* CERN, EMBL and ESO).

R&D grants awarded to public-sector units by:

Funds from institutions within the country:

- private enterprises
- government-sector institutions:
  - central and federal government units
  - provincial and state government units
  - local and municipal government units
  - public general university funds
- higher education sector institutions

- private non-profit institutions

Funds from institutions abroad

- private enterprises
- government-sector institutions
- higher education sector institutions
- private non-profit institutions
- European Union (*e.g.* Framework Programmes)
- international research organisations (*e.g.* CERN, EMBL and ESO).

5. BIOTECHNOLOGY R&D PERSONNEL

The decisive factor for the development of biotechnology is the presence in the country of highly qualified and trained personnel in the field. Units that have intramural biotechnology R&D expenditure necessarily have biotechnology R&D personnel to carry out their R&D projects.

Biotechnology R&D personnel should be broken down by occupation and by level of qualification. Disaggregated data by sex and citizenship are recommended.

5.1. By occupation

R&D personnel are classified by occupation based on the International Standard Classification of Occupations (ISCO-88). ISCO-88 will be replaced by ISCO-08 in the future.

Occupation

- biotechnology researchers (Major Group 2: professionals; and Unit Group 1237: research and development department managers, ISCO-88);
- biotechnology technicians (Major Group 3: associate professionals, ISCO-88);
- other biotechnology R&D supporting staff (Major Group 4: clerks; Major Group 6: skilled agricultural and fishery workers; Major Group 8: plant and machine operators and assemblers, ISCO-88).

5.2. By level of qualification

R&D personnel are classified by formal qualification based on the International Standard Classification of Education (ISCED-97).

Level of qualification (highest level attained)

- tertiary level, higher educational institutions (level 5A, ISCED-97)

  of which: PhD (level 6, ISCED-97)
- tertiary level, higher vocational education (level 5B, ISCED-97)
- upper secondary level (level 4, ISCED-97)
- other qualifications
- non-specified qualifications.

6. BIOTECHNOLOGY R&D COLLABORATION

Research collaboration between researchers at institutions of different sectors (*e.g.* between the government sector and the higher education sector or between the private sector and the higher education sector) is increasingly common. It would be worth collecting this type of information in order to monitor this trend.

Real collaboration is collaboration where both partners are engaged in research.

If it is difficult to obtain quantitative data on real collaborations, data on biotechnology R&D contracts can be used as data on collaboration between institutions. In fact, because a contract generally implies a certain level of follow-up and control of the work commissioned on the part of the contract awarder, this means of R&D funding can be a good indicator of collaboration between institutions.

If the breakdown of intramural R&D funding and of extramural R&D expenditure is sufficiently detailed (§ 4.4 and § 8.1), it becomes possible to ascertain with which sector collaboration has taken place.

A question concerning real collaboration could be formulated and broken down as follows:

6.1. By the institutional sector of the partner institutions

Collaboration with institutions within the country:

- private enterprises
- government-sector institutions
- higher education sector institutions
- private non-profit institutions.

Collaboration with institutions abroad:

- private enterprises
- government-sector institutions
- higher education sector institutions
- private non-profit institutions
- international research organisations (*e.g.* CERN, EMBL and ESO).

6.2. By field of biotechnology application and institutional sector of the partner institutions

It can be of interest to know in which field of biotechnology application the collaboration takes place.

7. PATENTS AND OTHER FORMS OF BIOTECHNOLOGY R&D COMMERCIALISATION

Public-sector units that perform biotechnology R&D frequently file patents to protect their inventions or engage in other forms of commercialisation, such as licensing or sales of patents or establishment of start-up companies. In addition, the public sector can acquire licences to patents and other forms of intellectual property for a fee. It would be worthwhile including a question on this topic in the questionnaire to learn more about public-sector activity in the filing and purchasing of patents and other forms of commercialisation.

8. EXTRAMURAL BIOTECHNOLOGY R&D EXPENDITURE

Public extramural biotechnology R&D expenditure corresponds to sums which a public-sector unit reports having paid or committed itself to pay to another unit for the performance of R&D during a specific period. This includes the acquisition of biotechnology R&D performed by other units (R&D contracts) and grants given to others to perform biotechnology R&D (R&D grants).

Public extramural biotechnology R&D expenditure corresponds to the public sector's funding of biotechnology R&D.

The sum of extramural expenditures of all public-sector units of the country constitutes total biotechnology R&D funding by the national public sector. Contracts and grants are the two major funding instruments available to the public sector.

For analytical purposes, it is preferable to record contracts and grants separately.

If the data are collected according to the breakdown proposed in § 8.3, it will be possible to calculate a number of very interesting aggregates, such as total public-sector biotechnology R&D contracts, total public-sector biotechnology R&D grants, total public biotechnology R&D funding in the country, total public biotechnology R&D funding abroad, and total public biotechnology R&D funding in each of the sectors (government and higher education) that constitute the public sector.

8.1. The public sector's biotechnology R&D contracts

R&D contracts are extramural expenditure used by the public sector to fund biotechnology R&D. Third parties are entrusted with biotechnology R&D contracts by public-sector bodies to perform biotechnology R&D for which they are paid. The contracts are usually governed by private law. The contract awarder (public sector) has a direct interest in using the results of the R&D to further its own activities; it may also supervise and monitor the performance of the R&D.

8.2. The public sector's biotechnology R&D grants

R&D grants are extramural expenditure used by the public sector to fund biotechnology R&D. Biotechnology R&D grants are non-refundable financial resources (grants) given to third parties by the public sector to encourage their biotechnology R&D activities. As a general rule, the grant awarder (the public sector) has little influence over the use of the R&D grants. It allocates and decides on grants. The use made of the financial resources made available is by and large determined by the recipient (beneficiary).

8.3. By beneficiary

The public sector's biotechnology R&D contracts and grants can be broken down by beneficiary:

Contracts awarded to institutions within the country:

- private enterprises
- government-sector institutions
- higher education sector institutions
- private non-profit institutions.

Contracts awarded to institutions abroad:

- private enterprises
- government-sector institutions
- higher education sector institutions
- private non-profit institutions
- international research organisations (*e.g.* CERN, EMBL and ESO).

Grants awarded to institutions within the country:

- private enterprises
- government-sector institutions
- higher education sector institutions
- private non-profit institutions.

Grants awarded to institutions abroad:

- private enterprises
- government-sector institutions
- higher education sector institutions
- private non-profit institutions
- European Union
- international research organisations (*e.g.* CERN, EMBL and ESO).

The public sector's biotechnology R&D contracts and grants can also be broken down:

8.4. by type of R&D

8.5. by field of science and technology

8.6. by field of biotechnology application

In practice however it will be difficult to collect these data. Government agencies, for example, probably will not know what percentage of their funding for university research goes to biotechnology, except for that part of funding which is targeted to biotechnology. Universities can fund part of their research from internal "own" sources (using student fees, endowments, etc.). These will not appear as extramural expenditure at any level.

9. MEASURES TO SUPPORT BIOTECHNOLOGY R&D OR BIOTECHNOLOGY INNOVATION

The public sector not only supports R&D by means of the R&D contracts and grants described in § 8. Many countries have established policies to encourage research and innovation. These policies usually involve all fields of R&D and innovation, but some are sometimes explicitly designed to encourage biotechnology R&D or innovation. Various types of measures (including tax incentives) can be adopted. It would be of interest to learn what they are and to record the public sector's financial participation in this area.

9.1. Examples of measures to support biotechnology R&D or biotechnology innovation

Creation of technology transfer centres (TTCs) and/or technoparks

The public sector sometimes helps fund TTCs and technoparks. TTCs are offices that provide various services to enterprises to assist in the creation or development of enterprises. Technoparks provide infrastructure for new enterprises.

Encouraging the development of regional industrial biotechnology clusters

The public sector sometimes assists in the development of regional industrial biotechnology clusters. Examples of such activities include providing assistance in transferring the results of biotechnology research from the academic world to local business sectors, assisting in evaluating the commercial potential of biotechnology research, and organising meetings between biotechnology scientists and appropriate industrial partners.

Support in the field of education

The presence of highly qualified personnel makes a country's development of biotechnology possible. If research enterprises or institutions do not find qualified personnel in the country, they can hire them from abroad. Some enterprises may simply choose to move abroad.

The public sector can allocate resources to encourage young people to study life sciences and biotechnology.

Tax incentives

Tax incentives or tax credits can be provided by governments to encourage the development of R&D biotechnology.

10. MODEL QUESTIONNAIRE AND APPENDIX

In order to avoid putting an undue burden on the units surveyed, a short model questionnaire is proposed in Annex 1. This questionnaire includes only the most important questions, those that provide the key indicators needed. Therefore the model questionnaire does not systematically include all the suggestions made in the guidelines. In fact, the breakdowns presented in the guidelines are not all equally relevant, nor do they all need to be developed to the same level of detail.

When an R&D survey in the public sector is made with the aid of an R&D questionnaire, the biotechnology R&D questionnaire can be added as an appendix module to the main questionnaire. As a result, biotechnology R&D expenditure will be obtained for the same year as total R&D expenditure. This will be an advantage for the subsequent analysis of the data.

The questionnaire includes an appendix for the person asked to answer the questionnaire. The appendix includes explanations on how to fill in the questionnaire and definitions of the terms employed.

Annex 1

Questionnaire on biotechnology research and development in the government and higher education sectors

Data protection	The information you provide will be kept strictly confidential. The survey findings will be published in such a way as to make it impossible for any conclusions to be drawn about your institution.
Survey period	Data refer to the period from 1 January 2010 to 31 December 2010.
Filling in the questionnaire	Please do not leave any fields blank. Indicate lack of expenditure or persons by "0". If you have trouble answering, please provide the best estimate possible. If you cannot itemise your information with the requested level of detail, please give at least an estimate of the total.
Deadline	Please return the completed form to us by:

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Definition of biotechnology

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.

DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.
Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors.
Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.
Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.
Gene and RNA vectors: Gene therapy, viral vectors.
Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.
Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.

Definition of research and experimental development (R&D)

Research and experimental development (R&D) comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications.

Definition of biotechnology R&D

Biotechnology research and experimental development (R&D) – defined as R&D into biotechnology techniques, biotechnology products or biotechnology processes, in accordance with both the biotechnology and R&D definitions presented above.

1. Contact person in your institution

Information about the person in your institution to contact for questions regarding this questionnaire.

Last name:
First name:
Title:
Department:
Telephone:
Email:

2. General data on your institution

Number of persons employed in your institution (R&D and non-R&D personnel) as of 31 December 2010 (in headcount units)		21
Annual budget of your institution in 2010 (in national currency (NC) '000)		22
Total intramural R&D expenditure by your institution (in NC '000)		23
Total extramural R&D expenditure by your institution (in NC '000)		24

A. Did your institution perform any intramural biotechnology R&D in 2010?

Yes ☐ Please go to section 3.

No ☐ Please go to screening question C.

3. Intramural biotechnology R&D expenditure

3.1 What was your institution's total intramural biotechnology R&D expenditure in 2010?

3.1. Total intramural biotechnology R&D expenditure

Total intramural biotechnology R&D expenditure (in NC '000)		**311**

3.2 What was the part of your institution's intramural expenditure by field of biotechnology application in 2010?

3.2. Distribution of total intramural biotechnology R&D expenditure by field of biotechnology application

Field of biotechnology application	**%**	
Health (human and animal)		321
Agriculture, aquaculture and silviculture		322
Food and beverages processing		323
Natural resources (mineral, petroleum mining, and other natural resources)		324
Environment		325
Industrial processing		326
Bioinformatics		327
Non-specific applications		328
Other		329
Total	**100% = point 311**	**3210**

4. Funding of intramural biotechnology R&D

4.1 How was your institution's total intramural biotechnology R&D expenditure financed in 2010?

4.1. Distribution of total intramural biotechnology R&D expenditure by funding type and source of funds

Funding type	**In NC '000**	
Own funds		411
Total biotechnology R&D contracts awarded to your institution		412
from within the country		413
of which awarded to your institution by the private enterprise sector in the country		414
from abroad		415
Total biotechnology R&D grants awarded to your institution		416
from within the country		417

of which awarded to your institution by the private enterprise sector in the country		418
from abroad		419
Total funding	**= point 311**	**4110**

4.2 Where did the funds to finance your institution's intramural biotechnology R&D activities come from in 2010?

4.2. Distribution of total intramural biotechnology R&D expenditure by source of funds

Source of funds from within the country	**In NC '000**	
Own funds		421
Biotechnology R&D contracts and grants awarded to your institution by:		
Private enterprises (contracts and grants)		422
Government-sector institutions (contracts and grants)		423
Higher education sector institutions (contracts and grants)		424
Private non-profit institutions (contracts and grants)		425
Total funding by contracts and grants from within the country		**426**
Source of funds from abroad		
Biotechnology R&D contracts and grants awarded to your institution by:		
Private enterprises (contracts and grants)		427
Other institutions (contracts and grants)		428
Total funding by contracts and grants from abroad		**429**
Total funding	**= point 311**	**4210**

5. Biotechnology R&D personnel

5.1 How many people participated in biotechnology R&D activities in your institution in 2010?

5.1. Distribution (in headcount units and full-time equivalence – FTEs) of biotechnology R&D personnel by occupation

Occupation	**Total in headcount**	**Total in FTEs**
Biotechnology researchers	511	5113
of which women	512	5114
of which with foreign citizenship	513	5115
Biotechnology technicians	514	5116
of which women	515	5117
of which with foreign citizenship	516	5118
Other biotechnology R&D support staff	517	5119
of which women	518	5120
of which with foreign citizenship	519	5121
Total biotechnology R&D personnel	**5110**	**5122**
of which women	5111	5123
of which with foreign citizenship	5112	5124

B. In 2010, did researchers at your institution collaborate with researchers of other institutions/enterprises in biotechnology R&D? Collaboration involves the active participation of two or more partners in research.

Yes ☐ Please go to section 6.

No ☐ Please go to screening question C.

6. Biotechnology R&D collaboration

6.1 Did researchers at your institution collaborate with other researchers (partners) on biotechnology R&D projects? Please indicate how many R&D collaborations were under way in 2010 by field of biotechnology application and institutional sector of the partner institutions.

6.1. Distribution of R&D collaborations by the field of biotechnology application and institutional sector of the partner institutions

	Institutional sector of the partner institutions				
Field of biotechnology application	**Private enterprises** (in number)	**Government-sector institutions** (in number)	**Higher education sector institutions** (in number)	**Private non-profit institutions** (in number)	**Collaborations abroad** (in number)
Health (human and animal)	611	6111	6121	6131	6141
Agriculture, aquaculture and silviculture	612	6112	6122	6132	6142
Food and beverages processing	613	6113	6123	6133	6143
Natural resources (mineral, petroleum mining, and other natural resources)	614	6114	6124	6134	6144
Environment	615	6115	6125	6135	6145
Industrial processing	616	6116	6126	6136	6146
Bioinformatics	617	6117	6127	6137	6147
Non-specific applications	618	6118	6128	6138	6148
Other	619	6119	6129	6139	6149
TOTAL	6110	6120	6130	6140	6150

6.2 What was your institution's intramural expenditure on collaboration in biotechnology R&D projects in 2010?

6.2. Distribution of intramural expenditure on collaboration in biotechnology R&D projects by institutional sector of the partner institutions

	Private enterprises (in NC '000)	**Government-sector institutions** (in NC '000)	**Higher education sector institutions** (in NC '000)	**Private non-profit institutions** (in NC '000)	**Collaborations abroad** (in NC '000)
Intramural expenditure on collaboration in biotechnology R&D projects with:	621	622	623	624	625

C. In 2010, did your institution file, or receive a grant, for any biotechnology patents?
In 2010, did your institution sell or buy any biotechnology patents or licences?
In 2010, did your institution found any biotechnology start-up companies?

Yes ☐ Please go to section 7.

No ☐ Please go to screening question D.

7. Patents and other forms of biotechnology R&D commercialisation

7.1 How many biotechnology patents did your institution file or have granted in 2010?
How many biotechnology start-up companies did your institution found in 2010?

7.1. Biotechnology patents filed or granted and biotechnology start-up companies founded

Number of biotechnology patents filed		711
Number of biotechnology patents granted		712
Number of biotechnology start-up companies founded		713

7.2 How much did your institution receive for the sale of biotechnology patents or licences in 2010?

7.2. Biotechnology patents or licences sold

Sold by your institution	Total 2010 income for sale of biotechnology patents or licences (in NC'000)	
Biotechnology patent sales		721
Biotechnology patent licensing		722
Total sales		723

7.3 How much did your institution spend for the purchase of biotechnology patents or licences in 2010?

7.3. Biotechnology patents or licences purchased

Purchased by your institution	Total 2010 expenditures for purchase of biotechnology patents or licences (in NC'000)	
From sellers in the country		731
From sellers abroad		732
Total purchases		733

D. In 2010, did your institution award any biotechnology R&D contracts or grants to third parties?

Yes ☐ Please go to section 8.

No ☐ Please go to screening question E.

8. Extramural biotechnology R&D expenditure

8.1 What was your institution's total extramural biotechnology R&D expenditure in 2010?

8.1. Total extramural biotechnology R&D expenditure

Total extramural biotechnology R&D expenditure (in NC '000)		**811**

8.2 What kind of funding instruments (contracts or grants) did your institution use for its extramural expenditure in 2010?

8.2. Distribution of total extramural biotechnology R&D expenditure by funding instruments (R&D contracts or grants)

Funding instruments	In NC '000	
Biotechnology R&D contracts		821
Biotechnology R&D grants		822
Total biotechnology R&D contracts and grants of your institution	**= point 811**	**823**

8.3 Who were the beneficiaries of your institutional support for biotechnology R&D projects in 2010?

8.3. Distribution of extramural biotechnology R&D expenditure by beneficiary

Beneficiary	In NC '000	
Biotechnology R&D contracts and grants of your institution awarded to		
Private enterprises		831
Government-sector institutions		832
Higher education sector institutions		833
Private non-profit institutions		834
Institutions abroad		835
Total biotechnology R&D contracts and grants of your institution	**= point 811**	**836**

E. Did your institution use any other financial or non-financial measures to support biotechnology R&D or biotechnology innovation in 2010?

Yes ☐ Please go to section 9.

No ☐ Please go to section 10.

9. Measures to support biotechnology R&D or biotechnology innovation

9.1 In 2010, which of the following measures did your institution support? Please put an X in the corresponding line of the first column if applicable.
How much did your institution spend (in NC '000) to support biotechnology with each of these measures?

Measures to support biotechnology R&D and biotechnology innovation	Yes	In NC '000	
Funding for technology transfer centres involved in biotechnology			91
Funding of technoparks for biotechnology enterprises			92
Assistance in transferring results of biotechnology research from the academic world to local business sectors, including small and medium-sized enterprises			93
Assistance in evaluating the commercial potential of biotechnology research			94
Organising meetings between biotechnology scientists and appropriate industrial partners			95
Support with negotiations and preparation of licensing and co-operation contracts, etc.			96
Measures in the field of biotechnology education and training			97
Other measures, including various tax incentives for R&D or innovation (please specify below)			98
			981
			982
			983
			984
Total			**99**

10. Comments and remarks

Thank you for participating!

Appendix
Biotechnology research and development in the government and higher education sectors
Instructions on filling in the questionnaire

I. GENERAL

Please keep in mind the following points when filling in the questionnaire:

- Refer to the definitions and explanations given in the appendix.

- **Do not leave any fields blank and indicate the absence of a response value by "0" (zero). If it is difficult for you to answer, please give the best estimate possible.**

- If you are unable to break down your information to the level of detail requested, please at least give an estimate of the total.

- All information regarding R&D refers to the calendar year 2010.

II. DEFINITIONS

1. DEFINITION OF RESEARCH AND DEVELOPMENT (R&D)

Research and experimental development (R&D) comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society and the use of this stock of knowledge to devise new applications.

R&D includes, in particular:

- Development of project planning and guidance (research management).
- Manufacture and testing of prototypes and further development leading up to production. However, this does not include the construction of production facilities.
- Building and running of pilot plants as long as these facilities are not used for normal production.
- Completion of projects based on new discoveries and scientific and/or technological progress, with the aim of clarifying uncertainties.

2. DEFINITION OF BIOTECHNOLOGY

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.

DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/ synthesis/amplification, gene expression profiling, and use of antisense technology.

Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors.

Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.

Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.

Gene and RNA vectors: Gene therapy, viral vectors.

Bioinformatics: Construction of databases on genomes, protein sequences; model-ling complex biological processes, including systems biology.

Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.

3. DEFINITION OF BIOTECHNOLOGY R&D

Biotechnology research and experimental development (R&D) – defined as R&D into biotechnology techniques, biotechnology products or biotechnology processes, in accordance with both the biotechnology and R&D definitions presented above.

III. EXPLANATIONS REGARDING THE SECTIONS OF THE QUESTIONNAIRE

1 Contact person in your institution

Information about the person in your institution to contact for questions regarding this questionnaire.

2 General information about your institution

Total number of persons employed in your institution as of 31 Dec. 2010 (headcount)	This refers to the number of persons (R&D and non-R&D personnel) employed (and not the number of positions) in your institution as of 31 December 2010 (full-time and part-time employees).
Total intramural R&D expenditure by your institution (in NC '000)	Intramural R&D expenditure refers to all R&D activities carried out by your institution on its own premises (laboratories) in the country, irrespective of how this R&D was funded. Intramural R&D expenditure is composed of expenditure on R&D personnel, other current R&D costs and investments in R&D (capital expenditure for R&D).
Total extramural R&D expenditure by your institution (in NC '000)	Extramural R&D expenditure includes all R&D activities that your institution has outsourced to third parties, whether in the form of contracts or grants. For the definition of "R&D contracts" and "R&D grants" see below, sections 4 et 8.

3 Intramural biotechnology R&D expenditure

3.1 Distribution of total intramural biotechnology R&D expenditure by expenditure type

Intramural biotechnology R&D expenditure is broken down as follows:

Labour costs of biotechnology R&D personnel	Labour costs of biotechnology R&D personnel include annual wages and salaries as well as personnel costs related to biotechnology R&D projects and benefits such as bonuses, holiday pay, employer contributions to retirement plan and other social security contributions (gross amounts).
Other current biotechnology R&D costs	Other current biotechnology R&D costs cover, with the exception of depreciation costs, all costs arising from rent, leasing, purchase of materials, supplies and various equipment that enable the performance of R&D and that are not part of the capital expenditure on biotechnology R&D (R&D investments).
Capital expenditure for biotechnology R&D	Capital expenditure for biotechnology R&D (investments in biotechnology R&D) covers expenditure for the acquisition of property and buildings, heavy-duty devices and equipment, as well as the purchase of software used for R&D activities. If acquisitions are not devoted entirely to R&D purposes, please give a rough percentage estimate of how much of the utilisation is R&D-related.

3.2 Distribution of total intramural biotechnology R&D expenditure by field of biotechnology application

Intramural biotechnology R&D expenditure can be broken down by field of biotechnology application. The fields of biotechnology application are defined as follows:

Broad	Intermediate	Detailed
Human health (with rDNA technology)	Large molecule therapeutics and monoclonal antibodies (MABs) produced using rDNA technology	
Human health ((without rDNA technology)	Other therapeutics, artificial substrates, diagnostics and drug delivery technologies, etc.	Other therapeutics, drug delivery technologies, etc. Substrates (artificial bone, skin, etc.). Diagnostics
Veterinary health	As above, for veterinary uses	Other therapeutics, drug delivery technologies, etc. Substrates (artificial bone, skin, etc.). Diagnostics
GM agriculture	New varieties of genetically modified (GM) plants, animals and micro-organisms for use in agriculture, aquaculture and silviculture	GM plants, including fruit trees, flowers, horticultural crops, grains, etc. GM animals for agriculture GM fish GM tree varieties for forestry GM micro-organisms for agriculture (including bio-pest control)
Non-GM agriculture	New varieties of non-GM plants, animals and micro-organisms for use in agriculture, silviculture, bio-pest control and diagnostics **developed using biotechnology techniques** (DNA markers, tissue culture, etc.)	Non-GM plants, including fruit trees, flowers, horticultural crops, grains, etc. Non-GM animals for agriculture Non-GM fish Non-GM tree varieties for forestry Non-GM micro-organisms for agriculture (including bio-pest control) Diagnostics
Food and beverages processing	Bio-processing, nutraceuticals, functional foods	Use of bio-processing or improved crop varieties to improve food quality and characteristics
Natural resources	Applications for mining, petroleum/energy extraction, etc.	Mining: extraction using micro-organisms, etc. Petroleum/energy: extraction using micro-organisms Other resource applications
Environment	Diagnostics, soil bioremediation, treatment of water, air and industrial effluents using micro-organisms, clean production processes	Diagnostics Soil bioremediation, including phytoremediation Effluent treatment Clean production processes
Industrial processing	Bioreactors to produce new products (chemicals, food, ethanol, plastics, etc.), biotechnologies to transform inputs (bioleaching, biopulping, etc.)	
Bioinformatics	Genomics and molecular modelling	DNA/RNA/protein synthesis and databases for humans, plants, animals and micro-organisms. Gene identification, gene constructs, etc.
Non-specific applications	Research tools, etc.	
Other		

Source: OECD, *A Framework for Biotechnology Statistics,* p. 37 (revised).

4 Funding of intramural biotechnology R&D

An institution's intramural biotechnology R&D is mainly funded *via* two major funding instruments (funding types): R&D contracts awarded by third parties and R&D grants given by third parties.

Biotechnology R&D contracts and grants are defined as follows:

Biotechnology R&D contracts	The institution is entrusted with biotechnology R&D contracts by external bodies to perform biotechnology R&D for remuneration. The contracts are usually governed by private law. The contract awarder has a direct interest in using the results of the R&D to further its own activities; it may also supervise and monitor the performance of the R&D.
Biotechnology R&D grants	Biotechnology R&D grants are financial resources given as non-recoverable grants by third parties to the institution to encourage its R&D activities. The grant awarder does not have a direct interest in the results of the R&D. It allocates and decides on grants. The use of the financial resources made available is by and large determined by the recipient. As a general rule, the provider of funds cannot influence the outcome of the R&D project. All the basic funding from the state is considered as grants.

5 Biotechnology R&D personnel

Biotechnology R&D personnel	The number of persons who directly carry out biotechnology R&D activities, including direct research, management and administration of biotechnology R&D projects, or supervision and guidance in relation to biotechnology R&D contracts and grants.
Full-time equivalence (FTE) on R&D	The second column (FTE) represents the total amount of working time devoted to biotechnology R&D in 2010. One full-time equivalence on R&D is the equivalent of one R&D employee working full-time for one year. Full-time equivalence on R&D is calculated by taking the type of workweek (full-time or part-time %), the duration of employment, and the portion of time devoted to R&D and multiplying these figures together.

Biotechnology R&D personnel is considered here according to **occupation**.
Indicate all persons who worked on biotechnology R&D in your institution in 2010, including those who worked on a temporary basis on short-term projects.

Biotechnology researchers	Biotechnology researchers are specialists who work on designing or creating new biotechnology R&D knowledge, products, procedures, methods and systems. This category also includes scientists who administer biotechnology R&D projects or co-ordinate the scientific and technical aspects of R&D work.
Biotechnology technicians	Biotechnology technicians are in charge of scientific, technical and laboratory work, normally under the supervision of researchers.
Other biotechnology R&D support staff	Other biotechnology R&D support staff includes administrative employees and other office workers who take part or are directly involved in biotechnology R&D projects. This category also includes managers and senior managers who are mainly involved in the financial, personnel-related and general administrative aspects of biotechnology R&D and lend direct support to biotechnology R&D activities.

6 Biotechnology R&D collaboration

Collaboration is defined as the public sector's biotechnology projects carried out in collaboration with other institutions. Real collaboration is collaboration in which both partners are engaged in research; it is not real collaboration when one partner conducts the R&D and the other pays for it. Collaboration by field of biotechnology application and by the sector in which the collaboration took place should be indicated in number of biotechnology R&D collaborations in the table.

7 Patents and other forms of biotechnology R&D commercialisation

Only the patents, licences and start-up companies in the field of biotechnology that have been filed, granted, sold, bought or founded by your institution (according to the definition of biotechnology) should be indicated in this section.

8 Extramural biotechnology R&D expenditure

Extramural biotechnology R&D expenditure includes all biotechnology R&D activities that your institution has outsourced to third parties, whether in the form of contracts or grants.

Biotechnology R&D contracts	The institution is entrusted with biotechnology R&D contracts by external bodies to perform biotechnology R&D for remuneration. The contracts are usually governed by private law. The contract awarder (public-sector financer) has a direct interest in using the results of the R&D to further its own activities; it may also supervise and monitor the performance of the R&D.
Biotechnology R&D grants	Biotechnology R&D grants are financial resources given as non-recoverable grants to third parties to encourage their biotechnology R&D activities. The grant awarder (public sector) does not have a direct interest in the results of the R&D. It allocates and decides on grants. The use of the financial resources made available is by and large determined by the recipient. As a general rule, the provider of funds cannot influence the outcome of the R&D project.

9 Measures to support biotechnology R&D or biotechnology innovation

List all measures taken by your institution to encourage biotechnology R&D and biotechnology innovation (including tax incentives). Assess their costs in 2010 for your institution.