



# Methodological report Biotechnology and nanotechnology

Warsaw, Szczecin 2023





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Objective scope of the survey / field	Biotechnology and nanotechnology activities, including research and experimental develop- ment
The type and method of the survey / field	Full survey
Data collection tools / data sources	<b>Tools</b> : on-line questionnaire on the Reporting Portal (PS) IT system of the survey (SIB)
	<b>Datasets of Statistics Poland:</b> MN-01 Questionnaire on biotechnology research and experimental development MN-02 Questionnaire on biotechnology in business enterprises PNT-05 Questionnaire on nanotechnology research and experimental development PNT-06 Questionnaire on nanotechnology in business enterprises
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# Main abbreviations

Abbreviation	Meaning
BDL	Local Data Bank
BDM	Macroeconomic Data Bank
BERD	Business enterprise expenditure on R&D
BES	Business enterprise sector
BF	Biotechnology firm
BJS	Base of Statistical Units
BRDF	R&D firm
DBF	Dedicated biotechnology firm
DBW	Knowledge Database
EU	European Union
Eurostat	Statistical Office of the European Union
FTE	Full-time equivalent
GERD	Gross domestic expenditure on R&D
GOV	Government sector
GUS	Statistics Poland
HES	Higher education sector
ISCED	International Standard Classification of Education
OECD	Organisation for Economic Cooperation and Development
PBSSP	Statistical survey program of official statistics
PKD	Polish Classification of Activities
PNP	Private non-profit sector
PS	Reporting Portal
R&D	Research and experimental development
SIB	IT system of the survey

### Introduction

Measuring and analysing information collected via biotechnology and nanotechnology surveys in Poland is possible thanks to data collected by Statistics Poland within *Biotechnology and Nanotechnology surveys* (definitions of terms are included in chapter 6) included in the Statistical survey program of official statistics (PBSSP) – surveys 1.43.12 and 1.43.17, respectively.

The methodology of biotechnology and nanotechnology surveys as well as definitions of terms related to this field have been developed by the OECD and are included in the following documents:

- Framework for Biotechnology Statistics (2005),
- Guidelines for a Harmonised Statistical Approach to Biotechnology Research and
- Development in the Government and Higher Education Sectors (2009),
- Revised proposal for the revision of the statistical definitions of biotechnology and nanotechnology (2018).

Moreover, the survey methodology complies with guidelines developed by EUROSTAT and the OECD included in *the Frascati Manual 2015*. Implementing guidelines regarding collecting and presenting data on research and experimental development included in the Manual ensures international comparability of biotechnology and nanotechnology R&D data.

Commission Implementing Regulation (EU) 2020/1197 of 30 July 2020 laying down technical specifications and arrangements pursuant to Regulation (EU) 2019/2152 of the European Parliament and of the Council on European business statistics repealing 10 legal acts in the field of business statistics (OJ L 271, 18.8.2020, p. 1-170, as amended) is an international law instrument from which stems an obligation to implement the surveys.

The Act of 29 June 1995 on Official Statistics (Journal of Laws of 2023, item 773) and the annual regulations of the Council of Ministers concerning the Statistical survey program of official statistics (PBSSP) establishing the survey programme for a given year constitute the basis for conducting biotechnology and nanotechnology surveys in Poland

In the Polish Classification of Activities (PKD 2007) a subclass 72.11.Z – *Research and experimental development on biotechnology* has been singled out of section M – *Professional, scientific and technical activities*. It is a useful classification to identify units for which biotechnology R&D is the main activity. However, biotechnology activities are conducted within or in addition to the main field of activity for the majority of units

Currently, nanotechnology branches have not been singled out at any level of classifications of economic activities – international (ISIC Rev. 4), the EU (NACE Rev. 2) and national (PKD 2007). For the majority of enterprises, nanotechnology activities are conducted within or in addition to the main economic activity.

An aim of the survey is providing information on biotechnology and nanotechnology in Poland. Both surveys concern new technologies and are similar in a number of issues. Moreover, they have been conducted on an ongoing basis, which enables providing information concerning changes in information resources related to biotechnology and nanotechnology.

The following publication presents the methodology of conducted surveys on biotechnology and nanotechnology. It comprises of ten chapters. The first chapter concerns subjective and objective scope of the surveys, the second one - the survey type and method. In the subsequent chapters data sources, variables used in the surveys, measures, indicators and calculating methods, definitions of key terms, organisation and management of survey implementation, data presentation and evaluation of survey quality are presented.

Data on biotechnology have been collected annually by Statistics Poland since 2008 with the use of questionnaire (dataset) MN-01 *Questionnaire on biotechnology research and experimental development*, while information regarding biotechnology in firms with the use of questionnaire (dataset) MN-02 *Questionnaire on biotechnology in business enterprises*. Data are collected annually in April/May.

The nanotechnology survey was conducted for the first time in 2012 as a pilot survey in scientific units with the use questionnaire (dataset) PNT-05 and in enterprises with the use of questionnaire (dataset) PNT-06. Due to non-mandatory nature of a pilot survey and low level of completeness resulting from it, results of a pilot survey were not published. Findings from a pilot survey allowed refining questionnaires (datasets). Starting with the Programme of statistical surveys of official statistics for the year 2017, the survey was permanently introduced as Nanotechnology and has been conducted annually in April/May. Surveys conducted over the years permitted recognising specifics of Polish experiences related to biotechnology and nanotechnology. During this time recommendations included in the Frascati Manual and the ones developed by the OECD have been adjusted to the development of biotechnology and nanotechnology surveys in Poland. Surveys dedicated to new technologies present certain difficulties already during creating a survey file because in Polish legislation only the Polish Classification of Activities - subclass 72.11.Z define biotechnology surveys, however, nanotechnology and biotechnology production do not have proper designations in the Polish Classification of Activities. The fact that new entities can be established in real time and may not be included in the survey on an on-going basis is another problem. Using web scraping technique is planned in the future in order to try to eliminate described complications.

# 1. Subjective and objective scope

### 1.1. Biotechnology

#### **Subjective scope**

The biotechnology survey is conducted separately for scientific units and firms.

The survey MN-01 Questionnaire on biotechnology research and experimental development covers the following units:

- scientific units, including units of the Polish Academy of Science, research institutes and higher education institutions, international research institutes operating on the territory of the Republic of Poland;
- other scientific units conducting research continuously, entities dedicated to science,
- units conducting postgraduate and doctoral studies, and granting scholarships.

According to the Polish Classification of Activities (PKD) the survey covers legal persons, organisational units without legal personality whose activities are classified into division 72 (class 72.11 and 72.19) - Scientific research and development, subclass 85.42.Z – Tertiary education and subclass 94.99.Z - Activities of other membership organisations n.e.c., regardless of the number of persons employed.

The survey MN-02 Questionnaire on biotechnology in business enterprises covers the following units:

• legal persons, organisational units without legal personality and natural persons conducting economic activities engaged in biotechnology, regardless of the number of persons employed and the type of activity.

Three categories of firms are distinguished in biotechnology surveys according to recommendations of the OECD:

#### Biotechnology firm (BF)

• a firm engaged in biotechnology using at least one biotechnology technique (as defined in the OECD list-based definition of biotechnology techniques) to produce goods or services and/or to perform biotechnology R&D;

#### Dedicated biotechnology firm (DBF)

a firm whose main activity involves application of at least one biotechnology technique to produce goods or services and/or to perform biotechnology R&D. Production of goods or services constitutes at least 75% of total production (including knowledge products created by R&D)

#### R&D firm (BRDF)

• a firm incurring intramural expenditures on R&D. Dedicated R&D firms (DBRDF) are distinguished within this category as the ones whose expenditures on biotechnology R&D amount to at least 75% of total R&D expenditures.

Size classes of firms are defined as follows:

- small firms employing up to 49 persons,
- medium firms employing 50-249 persons,
- large firms employing at least 250 persons.

#### **Objective scope**

The objective scope of the survey is developing and using biotechnology in scientific units and firms.

Key variables include:

- types of used techniques in biotechnology and areas of application,
- intramural expenditures by source of funding and areas of biotechnology application,
- financing biotechnology outside a reporting unit,
- personnel in biotechnology,

- biotechnology sales,
- submitted patent applications and granted patents in biotechnology,
- barriers in biotechnology,
- scientific and partner co-operation,
- purchases of patents and licences,
- using a closed circle economy.

The biotechnology activity covers:

- research and experimental development basic research applied research and experimental development with regard to techniques applied in biotechnology, biotechnology products or processes in accordance with both biotechnology definitions (presented in chapter 6),
- production in which biotechnology techniques are applied to manufacture products or in biotechnology processes, including environmental protection.

The statistical survey on biotechnology goes beyond the R&D sphere since, apart from entities carrying out biotechnology R&D, it also covers entities participating in biotechnology by applying at least one biotechnology technique (in accordance with the definition of biotechnology based on the OECD list of techniques) to manufacture goods or services.

The methodology of statistical surveys on biotechnology and definitions of used terms have been elaborated by the Organisation for Economic Co-operation and Development (OECD) and are included in the following documents:

- Framework for Biotechnology Statistics (2005),
- Guidelines for a Harmonised Statistical Approach to Biotechnology Research and Development in the Government and Higher Education Sectors (2009),
- Revised proposal for the revision of the statistical definitions of biotechnology and nanotechnology (2018).

The first document contains basic definitions related to biotechnology – both research and experimental development as well as application of biotechnology techniques to manufacturing goods and services. It focuses on the procedure of a statistical survey of this sphere of activities in the business enterprise sector. The second one – presents a harmonised approach to collecting and analysing statistical data on public sector biotechnology R&D which consists of two institutional sectors (in accordance with the Frascati Manual 2015) – the government and higher education sector. Both documents present model questionnaires – the first one – for the business enterprise sector, the second one – for the government and higher education sector.

Definitions of terms related to biotechnology R&D are consistent with terms used in surveys on the R&D sphere. Due to specificity of biotechnology, a "double definition" of biotechnology, i.e. single and list-based, is used for statistical purposes. In the case of measuring phenomena related to technology, the OECD methodological framework recommends using both concise and broad definitions of a given technology, supplemented with a list of examples.

The methodology of the biotechnology survey is in line with recommendations of the Frascati Manual.

#### 1.2. Nanotechnology

#### **Subjective scope**

The nanotechnology survey is conducted separately for scientific units and firms.

The survey PNT-05 Questionnaire on nanotechnology research and experimental development covers the following units:

- scientific units, including units of the Polish Academy of Science, research institutes and higher education institutions, international research institutes operating on the territory of the Republic of Poland,
- other scientific units conducting research continuously, entities dedicated to science,
- units conducting postgraduate and doctoral studies, and granting scholarships.

According to the Polish Classification of Activities (PKD), the survey covers legal persons, organisational units without legal personality whose activities are classified into division 72 (class 72.11 and 72.19) - Scientific research and development, subclass 85.42.Z – Tertiary education and subclass 94.99.Z - Activities of other membership organisations n.e.c., regardless of the number of persons employed.

The survey PNT-06 Questionnaire on nanotechnology in business enterprises covers the following units:

• legal persons, organisational units without legal personality and natural persons conducting economic activities engaged in biotechnology, regardless of the number of persons employed and the type of activity.

#### **Objective scope**

An objective scope of the survey is developing and using nanotechnology in scientific units and firms. Variables included in the Polish questionnaire (dataset) have been developed on the basis of the OECD questionnaire and the biotechnology survey.

Key variables include:

- using nanotechnology and areas of application,
- intramural expenditures by source of funding and area of nanotechnology application,
- financing nanotechnology outside a reporting unit,
- personnel in nanotechnology,
- nanotechnology sales,
- submitted patent applications and granted patents in nanotechnology,
- scientific and partner co-operation,
- purchases of patents and licences.

For the purpose of the statistical survey, the following applications of nanotechnology are distinguished:

- nanomaterials,
- nanoelectronics,
- nanooptics,
- nanophotonics,
- nanobiotechnology,
- nanomedicine,
- nanomagnetics,
- nanomechanics,
- filtration and membranes,
- nanotools,
- nanoinstruments and nanodevices,
- catalysis,
- modelling and simulation software.

The above-mentioned list of areas of nanotechnology applications is indicative rather than exhaustive and is expected to change over time as nanotechnology evolves.

The nanotechnology activity covers:

- research and experimental development basic, applied and industrial research as well as experimental development,
- production in which nanotechnology is used to manufacture goods.

The statistical survey on nanotechnology goes beyond the R&D sphere since, apart from entities carrying out nanotechnology R&D, it also covers entities participating in nanotechnology by manufacturing goods or services in one area of its application (in accordance with the definition of nanotechnology based on the OECD list of areas of application).

The methodology of statistical surveys on nanotechnology and definitions of used terms have been elaborated on the basis of methodological framework developed by the Organisation for Economic Co-operation and Development (OECD) included in the document Statistical Framework for Nanotechnology, 2011. This document contains basic definitions related to nanotechnology also with the use of application of nanotechnology techniques / areas of their application to manufacture goods and services. It presents a model statistical questionnaire used in a pilot survey conducted in five countries. Additionally, maintaining coherence with biotechnology surveys methodology was sought during the development of nanotechnology surveys methodology – also with research and experimental development survey of the whole R&D sphere.

Definitions of terms related to nanotechnology R&D are consistent with terms used in surveys on the R&D sphere. Due to specificity of nanotechnology, a "double definition" of nanotechnology, i.e. single and list-based, is used for statistical purposes. In the case of measuring phenomena related to technology, the OECD methodological framework recommends using both concise and broad definitions of a given technology, supplemented with a list of examples.

The methodology of nanotechnology survey is in line with recommendations of the Frascati Manual.

### 2. Survey type and method

Biotechnology and nanotechnology indictors are collected via a mandatory full-scale survey conducted every year.

Data within the survey 1.43.12 Biotechnology are collected with the use of questionnaires (datasets):

- MN-01 Questionnaire on biotechnology research and experimental development
- MN-02 Questionnaire on biotechnology in business enterprises

Data within the survey 1.43.17 Nanotechnology are collected with the use of questionnaires (datasets):

- PNT-05 Questionnaire on nanotechnology research and experimental development
- PNT-06 Questionnaire on nanotechnology in business enterprises

The statistical population is determined on the basis of entities included in the Base of Statistical Units (BJS).

The selection of units to the survey file takes place on the basis of various types of information sources. Sources of selecting units include, among others:

- 1. Data collected with the use of datasets (questionnaires):
  - *PNT-01 Report on research and experimental development (R&D) –* includes entities which indicated incurring intramural expenditures on biotechnology or nanotechnology,
  - *PNT-02 Questionnaire on innovations* includes entities which indicated conducting biotechnology or nano-technology activities.
- 2. Administrative sources:
  - a list of entities which signed an agreement with the National Centre for Research and Development to conduct biotechnology or nanotechnology projects;
  - a list of entities which received funds from the National Centre for Research and Development for biotechnology or nanotechnology R&D projects;
  - a list of entities which received funds from the National Science Centre for biotechnology or nanotechnology R&D;
  - a list of entities whom the Patent Office of the Republic of Poland granted patent for an invention during the survey year related to biotechnology or nanotechnology;

Sources of selecting entities to the survey files, apart from those mentioned above, include various type of information indicating that a given entity conducts or may conduct biotechnology or nanotechnology activities, such as information from websites of entities, press articles, conference materials as well as various rankings and lists.

### 3. Data gathering tools/data sources

A basic tool for gathering data within biotechnology and nanotechnology surveys are the following questionnaires (datasets):

- MN-01 Questionnaire on biotechnology research and experimental development,
- MN-02 Questionnaire on biotechnology in business enterprises,
- PNT-05 Questionnaire on nanotechnology research and experimental development,
- PNT-06 Questionnaire on nanotechnology in business enterprises.

National economy entities covered by a reporting obligation are requested to submit data in an electronic form via the Reporting Portal of Statistics Poland which enables filling in questionnaires (datasets) on-line (Computer Assisted Web Interview method – CAWI). Logging in is possible via an account activated previously. The procedure of setting up an account is described in the Guide to electronic reporting available on the Reporting Portal website: <u>http://form.stat.gov.pl/formularze/</u>przewodnik/psinfo.htm.

An electronic version of questionnaires on the Reporting Portal enables logical and calculating control of data entered into questionnaires (datasets) as well as controlling coherence between their sections.

Two types of errors can be distinguished, namely absolute errors which do not allow accepting a questionnaire and discretionary errors which are informative only and do not block such possibility. In the case of absolute errors, data should be corrected. In order to correct an error, a respondent should reach out to a contact person for substantive issues. Discretionary errors concern, for example not answering a question about time dedicated to preparing data and filling in a questionnaire or a request to explain lack of sales. Accepting data on the Reporting Portal means meeting a reporting obligation by an entity

Depending on a type of question answers are given via:

- ticking a correct answer, e.g. in yes/no questions,
- providing a numeric value in a box in questions concerning, i.a. the value of expenditures or the number of personnel,
- providing text in a box in questions concerning, i.a. data concerning an entity or a comment,
- selecting a correct answer from a list from a so-called 'glossary'.

Model questionnaires (datasets) MN-01, MN-02, PNT-05 and PNT-06 constitute annex no. 1-4 to the following publication and are available on the website <u>http://form.stat.gov.pl/formularze/2023</u>

After closing the survey edition on the Reporting Portal, further works are conducted in the IT system of the survey.

### 4. Variables used in surveys

Presented below variables are most frequently included in publications and databases, for example Biotechnology and nanotechnology in Poland, Science and technology, BDL, DBW.

The variables (both qualitative and quantitative) presented in annexes 5-8 are compiled with the use of biotechnology and nanotechnology questionnaires. Both qualitative as well as quantitative variables are collected.

Qualitative variables concern, i.a.:

- conducting biotechnology or nanotechnology activities,
- using a closed circle economy in a biotechnology firm.

Quantitative variables include, i.a.:

- biotechnology or nanotechnology intramural expenditures this variable determines the amount of incurred expenditures performed within a unit during a reporting year;
- biotechnology and nanotechnology sales this variable determines the value of sales of products (goods and services) manufactured as a result of biotechnology and nanotechnology activities;
- biotechnology and nanotechnology R&D personnel this variable determines the number of personnel engaged in research and experimental development performed within a unit;
- biotechnology and nanotechnology patent applications and patents granted this variable determines the number of submitted patent applications and patents granted by competent institutions.

Mentioned above quantitative variables are collected with the use of questionnaires (datasets) MN-01, MN-02, PNT-05 and PNT-06.

Detailed lists of variables are included in annexes 5 - 8 and are available on the website: Detailed format of provided data in 2023 (stat.gov.pl)

# 5. Indicators and calculating methods

### 5.1. Biotechnology

The most frequently used biotechnology indicators:

- R&D biotechnology entities this indicator constitutes the number of entities conducting biotechnology research and experimental development or financing performance of such activities by other entity during a reporting year. It is presented in publications and databases of Statistics Poland in natural numbers.
- Intramural biotechnology R&D expenditures are presented in statistics as aggregated values. Data in this regard are presented in publications and databases of Statistics Poland in thousand or million PLN and:
  - in a breakdown by sectors of performance business enterprise sector, higher education sector, government sector (including private non-profit sector),
  - as a ratio of intramural biotechnology R&D expenditures to gross domestic expenditure on R&D (GERD) the quotient of biotechnology intramural expenditures to gross domestic expenditure on R&D (GERD) is used to calculate this indicator.
- Biotechnology R&D personnel includes all persons engaged directly in biotechnology research and experimental
  development, regardless of the source of funds for their emolument and regardless of whether a person is employed in other reporting units; it includes persons working in Poland as well as abroad for units in which they are
  employed. The number of persons constituting internal personnel in biotechnology R&D is determined on the basis
  of persons listed in the questionnaire MN-01 as internal personnel. Data on personnel are collected in headcount
  and full-time equivalents (FTE). Such data in biotechnology are presented in publications and databases of Statistics
  Poland in headcount and FTE as well as:
  - in a breakdown by sectors of performance business enterprise sector, higher education sector, government sector (including private non-profit sector),
  - by education level in accordance with the International Standard Classification of Education ISCED 2011.
- Number of biotechnology firms is a commonly used indicator of involvement of a given country in applying biotechnology. This indicator constitutes the number of units conducting biotechnology activities or financing performance of such activities by other entity during a reporting year. This indicator is presented as of 31 December. It is presented in publications and databases of Statistics Poland in natural numbers. When analysing activities of biotechnology firms, they are presented in breakdowns recommended by the OECD and generally accepted classifications of firms.
- Intramural expenditures of biotechnology firms are presented in statistics as aggregated values. Data in this regard are presented in publications and databases of Statistics Poland in thousand or million PLN and:
  - in a breakdown by biotechnology firms (BF), dedicated biotechnology firms (DBF) and R&D firms (BRDF);
  - as a ratio of intramural expenditures of biotechnology firms to business enterprise expenditure on R&D (BERD)
     the quotient of biotechnology intramural expenditures to business enterprise expenditure on R&D (BERD) in Poland is used to calculate this indicator.
- Personnel of biotechnology firms takes into account the number of persons employed in biotechnology R&D as well as the number of persons associated with manufacturing in biotechnology who are in a unit's register during a reporting year. Data on personnel are collected in headcount and full-time equivalents (FTE). Biotechnology data are presented in publications and databases of Statistics Poland in headcount and FTE as well as:
  - in a breakdown by biotechnology firms (BF), dedicated biotechnology firms (DBF) and R&D firms (BRDF),
  - by education level in accordance with The International Standard Classification of Education ISCED 2011.
- Sales of biotechnology products in firms are presented in statistics as aggregated values. Total value of biotechnology product sales (goods and services) performed during an indicated reporting period. Such data are presented in publications and databases of Statistics Poland in thousand or million PLN.

### 5.2. Nanotechnology

The most frequently used nanotechnology indicators:

- R&D nanotechnology entities this indicator constitutes the number of entities conducting nanotechnology research and experimental development or financing performance of such activities by other entity during a reporting year. It is presented in publications and databases of Statistics Poland in natural numbers.
- Intramural nanotechnology R&D expenditures are presented in statistics as aggregated values. Data in this regard are presented in publications and databases of Statistics Poland in thousand or million PLN and:
- in a breakdown by sectors of performance business enterprise sector, higher education sector, government sector (including private non-profit sector).
- Nanotechnology R&D personnel includes all persons engaged directly in nanotechnology research and experimental development, regardless of the source of funds for their emolument and regardless of whether a person is employed in other reporting units; it includes persons working in Poland as well as abroad for units in which they are employed. Data on personnel are collected in headcount and full-time equivalents (FTE). This indicator is presented in publications and databases of Statistics Poland in headcount and FTE as well as:
  - in a breakdown by sectors of performance (in accordance with explanations on p. 27) business enterprise sector, higher education sector, government sector (including private non-profit sector),
  - by education level in accordance with The International Standard Classification of Education ISCED 2011.
- Number of nanotechnology firms is a commonly used indicator of involvement of a given country in applying nanotechnology. This indicator constitutes the number of units conducting nanotechnology or financing performance of such activities by other entity (outside a reporting unit) during a reporting year. It is presented in publications and databases of Statistics Poland in natural numbers. When analysing activities of nanotechnology firms, they are presented in breakdowns recommended by the OECD and generally accepted classifications of firms.
- Intramural expenditures of nanotechnology firms are presented in statistics as aggregated values. Data in this
  regard are presented in publications and databases of Statistics Poland in thousand or million PLN.
- Personnel of nanotechnology firms takes into account the number of persons employed in nanotechnology R&D as well as the number of persons associated with manufacturing in nanotechnology who are in a unit's register during a reporting year. Data on personnel are collected in headcount and full-time equivalents (FTE). Nanotechnology data are presented in publications and databases of Statistics Poland in headcount and FTE as well as in a breakdown by education level – in accordance with The International Standard Classification of Education ISCED 2011.
- Sales of nanotechnology products in firms are presented in statistics as aggregated values. Total value of nano technology product sales (goods and services) performed during an indicated reporting period. Such data are presented in publications and databases of Statistics Poland in thousand or million PLN.

# 6. Definitions of key terms

### 6.1. Definitions used in biotechnology

A "double" definition of biotechnology, i.e. single and list-based, is used for statistical purposes.

• The single definition:

Biotechnology - the interdisciplinary 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<sup>1</sup>).

• The list-based definition:

This definition covers types of techniques applied in biotechnology (points from 1 to 7). Additionally, a detailed guide for reporting entities, on the basis of the OECD recommendations, including elaboration of every point for a list-based definition (listed by bullets) was prepared by the Statistical Office in Szczecin.

- 1. DNA/RNA: genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, the use of antisense technology, large-scale DNA synthesis, genome- and gene-editing, gene drive;
  - Genomics/pharmacogenomics the study of genes and their function. Advances in genomics due to the Human Genome Project and other genome research into plants, animals and micro-organisms are enhancing our understanding of the molecular mechanisms of genomes. Genomics stimulates the discovery of health care products by revealing thousands of new biological targets for the development of drugs and by identifying innovative ways to design new drugs, vaccines and DNA diagnostics. Genomic-based therapeutics includes both protein drugs and small molecule drugs. Genomics is also used in plant and animal breeding programmes;
  - Gene probes/DNA markers a section of DNA of known structure or function which is marked with a radioactive isotope, dye or enzyme so that it can be used to detect the presence of specific sequences of bases in another DNA or RNA molecule;
  - Genetic engineering altering the genetic material of cells or organisms in order to make them capable of making new substances or performing new functions;
  - DNA/RNA sequencing determination of the order of nucleotides (i.e. the base sequence) in a DNA or RNA molecule;
  - DNA/RNA synthesis the linking together of nucleotides to form DNA or RNA. In vivo, most synthesis involves DNA replication, but incorporation of precursors also occurs in repair. In the special case of retroviruses, an RNA template directs DNA synthesis;
  - DNA/RNA amplification the process of increasing the number of copies of a particular gene or gene-derived sequence;
  - Other there are several fields of research on RNA, including RNAi and siRNA, based on the use of recombinant technology to generate RNA sequences to inhibit gene function. Expression profiling analyses expressed genes using microarrays or gene chips.
- 2. Proteins and other molecules sequencing/synthesis/engineering of proteins and peptides, improved delivery methods for large molecule drugs, proteomics, protein isolation and purification, signaling, identification of cell receptors.
  - Peptide/Protein sequencing determination of the order of amino acids in a protein or peptide;
  - Peptide synthesis a procedure which links two or more amino acids in a linkage called a peptide bond;
  - Protein engineering the selective, deliberate (re)designing and synthesis of proteins. This is done in order to cause the resultant proteins to carry out desired (new) functions. Protein engineering is accomplished by changing or interchanging individual amino acids in a normal protein. This may be done via chemical synthesis or recombinant DNA technology (i.e. genetic engineering). "Protein engineers" (actually genetic engineers) use recombinant DNA technology to alter a particular nucleotide in the triplet codon of the DNA of a cell. In this way it is hoped that the resulting DNA codes for the different (new) amino acid in the desired location in the protein produced by that cell;

<sup>1</sup> According to the OECD definition developed in 2001.

- Proteomics analysis of the expression, functions and interactions of all proteins of an organism;
- Signaling analysis of signaling molecules such as cytokines, chemokines, transcription factors, cell cycle proteins, and neurotransmitters;
- Cell receptors:
  - surface proteins structures (typically proteins) found in the plasma membrane (surface) of cells that tightly bind specific molecules (organic molecules, proteins, viruses etc.).
  - integral proteins some (relatively rare) receptors are located inside the cell. Both (membrane and internal) types of receptors are a functional part of information transmission (i.e. signalling) of the cell.
- 3. Cell and tissue culture and engineering cell/tissue culture, tissue engineering, cellular fusion, vaccine/immune stimulants, embryo manipulation, marker assisted breeding technologies, metabolic engineering.
  - Cell/tissue/embryo culture and manipulation growth of cells, tissues or embryonic cells under laboratory conditions;
  - Tissue engineering: refers to the technologies used to induce:
    - (injected) liver, cartilage, etc., cells to grow (within a recipient organism's body) and form replacement [integral] tissues,
    - (extant) cells within the body encouraged to grow and form desired tissues, via precise injection of relevant compounds (e.g. certain growth factors, growth hormones, stem cells, etc.),
    - laboratory grown tissue or organs to replace or support the function of defective or injured body parts (e.g. skin tissue culture for grafts);
  - Cell fusion the combining of cell contents of two or more cells to become a single cell. Fertilisation is such a
    process
  - Vaccines/immune stimulants a preparation containing an antigen consisting of whole disease-causing organisms (killed or weakened), or parts of such organism is used to confer immunity against the disease that the organisms cause. Vaccine preparations can be natural, synthetic or derived by recombinant DNA technology.
- 4. Process biotechnology techniques fermentation using bioreactors, biorefining, bioengineering, biocatalysis, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biosensing, biofiltration and phytoremediation, molecular aquaculture.
  - Bioreactor a vessel in which cells, cell extracts or enzymes carry out a biological reaction. Often refers to a fermentation vessel for cells or micro-organisms;
  - Bioprocessing a process in which living cells or components are used to produce a product, especially a biological product involving genetic engineering for commercial use;
  - Bioleaching the conversion of metals to a soluble form by live organisms such as bacteria or fungi;
  - Biopulping use of micro-organisms to break down wood fibres for the purpose of producing pulp;
  - Biobleaching use of micro-organisms to bleach pulp;
  - Biodesulphurisation use of specific micro-organisms to transform hazardous sulphurs into less hazardous compounds;
  - Bioremediation/biofiltration/phytoremediation the process by which living organisms act to degrade hazardous organic contaminants or transform hazardous inorganic contaminants to environmentally safe levels in soils, subsurface materials, water, sludge, and residues.
    - bioremediation the use of micro-organisms to remedy environmental problems rendering hazardous wastes non-hazardous,
    - biofiltration the use of a support containing specific bacteria to capture by filtration hazardous substances from a gas stream,
    - phytoremediation refers to the use of specific plants to remove contaminants or pollutants from either soils (e.g. polluted fields) or water resources (e.g. polluted lakes).

- 5. Gene and RNA vectors gene therapy, phage therapy, viral vectors.
  - Gene therapy gene delivery, the insertion of genes (e.g. via retroviral vectors) into selected cells in the body in order to:
    - cause those cells to produce specific therapeutic agents,
    - cause those cells to become (more) susceptible to a conventional therapeutic agent that previously was ineffective against that particular condition/disease,
    - cause those cells to become less susceptible to a conventional therapeutic agent,
    - counter the effects of abnormal (damaged) tumour suppressor genes via insertion of normal tumour suppressor genes,
    - cause expression of ribozymes that cleave oncogenes (cancer-causing genes),
    - introduce other therapeutics into cells;
  - Phagotherapy the therapeutic use of bacteriophages (viruses only infecting bacteria) for the treatment of bacterial infections. Bacteriophages (also called phages) can efficiently destroy various bacteria, including the antibiotic resistant ones;
  - Viral vectors certain (retro-) viruses that are used by genetic engineers to carry new genes into cells.
- 6. Bioinformatics construction of databases on genomes, protein sequences, modelling complex biological processes, including systems biology.
  - The use of computers in solving information problems in the life sciences; mainly, it involves the creation of
    extensive electronic databases on genomes, protein sequences, etc. as well as techniques such as the threedimensional modelling of biomolecules;
  - The generation/creation, collection, storage (in databases), and efficient utilisation of data/information from genomics (functional genomics, structural genomics, etc.), combinatorial chemistry, high-throughput screening, proteomics, and DNA sequencing research efforts in order to accomplish a (research) objective (e.g. to discover a new pharmaceutical or a new herbicide, etc.). Examples of the data/information that is manipulated and stored include gene sequences, biological activity/function, pharmacological activity, biological structure, molecular structure, protein-protein interactions, and gene expression products/amounts/timing;
- 7. Nanobiotechnology applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics etc. It covers the interface between physics, biology, chemistry and the engineering sciences and aims to develop completely new measuring technologies for the biosciences. Nanotechnology develops or makes materials that function on a very small scale, typically between 1 and 100 nanometers. Nanobiotechnology uses these particles and materials as tools to improve the performance and sensitivity of several life science technologies, e.g. biosensing, medical devices and medical implants.

Research and experimental development (R&D) – creative and systematic work undertaken in order to increase the stock of knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge. An activity must fulfil five basic criteria to be considered R&D. The activity must be:

- novel aimed at new findings,
- creative based on original, not obvious concepts and hypotheses,
- uncertain uncertain about the final outcome or cost, including devoted time,
- systematic conducted in a planned way (the aim of the R&D project and the sources of funds must be defined),
- transferable and/or reproducible leading to results that could be reproduced.

Basic research – experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view.

Applied research - works aimed at the acquisition of new knowledge or skills, directed at developing new products, processes or services or for bringing about a significant improvement in them.

Experimental development – acquiring, linking, shaping and using available current knowledge and skills, including IT and programming tools, to plan production as well as design and create changed, improved or new products, processes or services, excluding changes introduced routine or periodic changes even if they constitute improvements.

Biotechnology production –biotechnology techniques are applied to manufacture biotechnology products or in biotechnology processes, including environmental protection.

Intramural biotechnology R&D expenditures – all current expenditures and gross fixed capital expenditures for R&D performed within a statistical unit during a reporting period, whatever the source of funds.

Gross capital expenditures - annual gross amount paid for the acquisition of fixed assets that are used repeatedly or continuously in the performance of R&D for more than one year. They should be reported in full for the period when they were incurred, regardless of whether acquired or developed in house, and should not be registered as an element of depreciation. Capital expenditures include:

- land acquired for R&D use (e.g. testing grounds, sites for laboratories and pilot plants);
- buildings constructed or purchased for R&D use, including major improvements, modifications and repairs;
- machinery and equipment- acquired for use in the performance of R&D. This category includes machinery, technical equipment, means of transport, tools, instruments, movable properties and equipment;
- computer software used in the performance of R&D for more than one year. It includes long-term licences or the
  acquisition of separately identifiable computer software, including program descriptions and supporting materials
  for both systems and applications software. The production costs (e.g. labour and materials) of internally produced
  software should be reported. Software from external vendors may be obtained through the outright purchase of
  rights or licences to use. Software used or licensed for one year or less should be reported under current expenditures;
- other intellectual property products costs of purchased patents, long-term licences or other intangible assets used in R&D which are used for more than one year.

The value of capital expenditures covers both expenditures on fixed assets linked to R&D put into use during a reporting year as well as expenditures incurred on ongoing investments during this period (i.e. on future fixed assets linked to R&D).

#### Current expenditures - include labour costs and other current costs.

Labour costs – compensation of internal R&D personnel in biotechnology, such as annual wages and salaries and all associated costs or fringe benefits, such as bonus payments, stock options, holiday pay, contributions to pension funds, other social security payments, payroll taxes and other overheads on salary as well as scholarships of doctoral studies participants conducting biotechnology R&D. In the case of owners, costs of paid social security contributions in a part corresponding to engagement in biotechnology R&D should be included in labour costs. It is important to include only labour costs for employed persons when they make a direct contribution to intramural biotechnology R&D, especially if such persons do not work full-time on biotechnology R&D. Labour costs shouldn't include costs of work of persons providing intermediary services, not included in data on biotechnology R&D personnel (e.g. security, administration, central library or IT department personnel) which in a part related to biotechnology R&D are included in current costs.

Other current costs include:

- costs for external services, i.a. services supporting an internal R&D biotechnology project, e.g.
  - outsourcing by a pharmaceutical company to a laboratory doing blood tests of patients taking part in research on new drugs. For a principal – a pharmaceutical company – it is a cost related to implementation of an R&D project, while for a contractor – a laboratory – it is routine work conducted in accordance with accepted standards and methods,
  - developing by an enterprise a concept of new software, use of which would streamline processes taking place in an enterprise and then outsourcing software creation to a software development company. For a principal it would be experimental development, while for a software company – conducting works without R&D characteristics;
- license fees for the use of intellectual property rights up to a year;
- costs for materials, non-durable articles, energy;

- costs for books, journals, reference materials, and subscriptions to libraries and scientific societies, etc.;
- costs for intermediary services, including: external processing, transport, renovation, security, banking, postal, ICT, publishing or municipal services, etc;
- costs of business trips;
- other current costs, including, in particular, taxes and fees charging costs of activity and profits;
- property insurance.

Expenditures associated with acquisition of formation of research equipment which meets criteria for inclusion in fixed assets and for which multiple and continuous use in R&D for more than one year is expected but which is not included in a fixed assets register till the end of R&D works shouldn't be included in current costs. Such expenditures should be included in capital expenditures.

Biotechnology expenditures – cover expenditures on activities of biotechnology firms. Biotechnology activity includes production of goods and/or services or R&D. Expenditures on manufacturing goods in a part related to biotechnology should be included in expenditures on production.

Internal R&D personnel in biotechnology – persons employed in a statistical unit who contribute to a unit's intramural R&D. It includes all persons engaged directly in R&D, regardless of whether they are employed by a statistical unit or are external contributors fully integrated into a statistical unit's R&D activities as well as those providing direct services for R&D activities (such as R&D managers, administrators, technicians and clerical staff).

Researchers – professionals conducting research and improving or developing concepts, theories, models, techniques, instrumentation, software or operational methods. Conducting R&D does not have to be based on formal qualifications or a job position. This category includes participants of doctoral studies conducing biotechnology R&D. The tasks of researchers especially involve:

- conducting research, experiments, tests and analyses,
- developing concepts, theories, models, techniques, instrumentation, software and operational methods,
- gathering, processing, evaluating, analysing, and interpreting research data,
- evaluating the results of investigations and experiments, and making conclusions using different techniques and models,
- applying principles, techniques and processes to develop or improve practical applications,
- advising on designing, planning and organising testing, construction,
- providing advice and support to governments, organisations and businesses on the application of research results,
- planning, directing and coordinating R&D conducted by institutions providing related services for other organisations,
- preparing scientific papers and reports.

Technicians and equivalent staff – persons participating in biotechnology R&D, performing scientific and technical tasks related to the application of concepts and operational methods and using research equipment, normally under the supervision of researchers. Equivalent staff perform biotechnology R&D tasks under the supervision of researchers. Their tasks include:

- carrying out bibliographic searches and selecting relevant material from archives and libraries,
- preparing computer programs,
- carrying out experiments, tests and analyses,
- providing technical assistance and support in R&D, or testing prototypes,
- operating, maintaining and repairing research equipment,
- preparing materials and equipment for experiments, test and analyses,
- recording measurements, making calculations and preparing charts and graphs,
- collecting information using accepted scientific methods,
- assisting in analysing data, keeping records and preparing reports,
- carrying out statistical surveys and interviews.

Other supporting staff – this category includes skilled and unskilled craftsmen, and administrative, secretarial and clerical staff participating in biotechnology R&D or directly associated with such works. This group also covers persons dealing with personnel and financial issues if their work is directly associated with biotechnology R&D, including administrative and clerical works as well as providing materials and equipment necessary to carry out a biotechnology R&D project or managing such materials and equipment. Personnel providing intermediary services, such as canteen, security or cleaning services, is excluded.

Production personnel –persons associated with biotechnology production. It includes persons directly employed in a production process, administrative, secretarial and clerical staff as well as management staff. If a person employed performs tasks related to production and R&D, he/she should be included in a group to which he/she dedicated the majority of working time.

Full-time equivalent (FTE) – a conversion unit defined as the ratio of working hours actually spent on biotechnology R&D during a reporting period (usually a calendar year) divided by the total number of hours conventionally worked in the same position by an individual or by a group. One full-time equivalent (FTE) means one person-year devoted exclusively to biotechnology R&D.

The business enterprise sector - private and public entities as well as non-profit institutions serving enterprises whose primary activity is the production of goods or services for sale at economically significant prices.

The government sector – units of state and local government as well as non-market non-profit institutions controlled by government sector units that are not part of the higher education sector.

Examples: scientific institutes of the Polish Academy of Sciences, research units, hospitals and clinics not providing training if they are controlled and financed by the government sector units.

The higher education sector - includes all universities, colleges of technology and other institutions providing formal tertiary education programmes, whatever their source of finance or legal status. It also includes university hospitals and clinics – whole or in part conducting biotechnology R&D as well as archives, libraries, museums, historical sites, botanical gardens administered by higher education institutions or affiliated with them.

The private non-profit sector – so-called non-profit institutions. Private non-profit institutions include foundations (e.g. the Foundation for Polish Science), political parties, trade unions, consumers' associations, societies and associations (professional, scientific, religious and other) as well as natural persons and organisations dealing with promoting, financing and other forms of supporting scientific research.

Biotechnology product - a good or service which development requires the use of one or more biotechnology techniques according to both biotechnology definitions (a list-based and single definition). It includes knowledge products (technical know-how) created from biotechnology R&D.

Biotechnology firm (BF) - a firm engaged in biotechnology by using at least one biotechnology technique (as defined in the OECD list-based definition of biotechnology techniques) to produce goods or services and/or to perform biotechnology R&D.

Dedicated biotechnology firm (DBF) - a firm whose main activity involves application of at least one biotechnology technique to produce goods or services and/or to perform biotechnology R&D. Production of goods or services constitutes at least 75% of total production (including knowledge products created by R&D).

R&D firm (BRDF) - a firm incurring intramural expenditures on R&D. Dedicated R&D firms (DBRDF) are distinguished within this category as the ones whose expenditures on biotechnology R&D amount to at least 75% of total R&D expenditures.

#### 6.2. Definitions used in nanotechnology

Nanotechnology - understanding and control of matter and processes at the nanometre-scale, typically but not exclusively below 100 nanometers, in one or more dimensions, where the onset of size-dependent phenomena usually enables novel applications. These applications utilise the properties of nanoscale materials that differ from the properties of individual atoms molecules to create improved materials devices and systems that exploit these new properties

Nanomaterial - means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %<sup>2</sup>.

<sup>2</sup> Commission Recommendation of 18 October 2011 on the definition of nanomaterial (OJL 275, 20.10.2011, p. 38-40)

Nanoelectronics – a field of electronics involving devices with dimensions in the realms of nanometres; operation of devices is based on physical phenomena related to very small areas in which electrons move. These phenomena can be divided into electrowave, single-electron and spin<sup>3</sup>.

Nanomedicine – nanotechnology research applied in medicine. Nanoparticles range from 1 to 100 nm constituting one millionth of a millimetre (1 nm = 10-9 m). For comparison, an average bacteria is a thousand times bigger (its size ranges from 1  $\mu$ m to 10  $\mu$ m), and a grain of sand can be even one hundred thousand times bigger4.

Basic research – experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts, without any particular application or use in view.

Applied research - original investigation undertaken in order to acquire new knowledge. It is, however, directed primarily towards a specific, practical aim or objective. Synonymous with application research defined in Article 4 on the Act of 20 July 2018 the Law on Higher Education and Science (Journal of Laws of 2018 item 1668) as works aimed at the acquisition of new knowledge or skills, directed at developing new products, processes or services or for bringing about a significant improvement in them.

Experimental development – acquiring, linking, shaping and using available current knowledge and skills, including IT and programming tools, to plan production as well as design and create changed, improved or new products, processes or services, excluding changes introduced routine or periodic changes even if they constitute improvements, for example:

- the development of projects, drawings, plans or other documents to create new products, processes and services provided they are not used for commercial purposes,
- the development of prototypes and pilot projects which can be used for commercial purposes if a prototype constitutes a final product ready for commercial use and its production only for demonstration or validation purposes is too expensive,
- activities related to experimental production or testing products, processes and services provided they are not used for commercial purposes.

Experimental development does not include routine and periodic changes made to products, production lines, manufacturing processes, existing services or other operations in progress even if such changes may represent improvements as well as pilot or demonstration projects used for commercial purposes.

Intramural expenditures – expenditures incurred during a reporting year on nanotechnology R&D performed within a statistical unit, whatever the source of funds. Nanotechnology R&D expenditures cover current expenditures and gross fixed capital expenditures but exclude depreciation of fixed assets and deductible part of value added tax (VAT). These expenditures are reported as incurred costs, that is - taking into account granted discounts or rebates.

Gross capital expenditures – expenditures related to nanotechnology R&D incurred during a reporting year defined as annual gross amount paid for the acquisition of fixed assets that are used repeatedly or continuously in the performance of R&D for more than one year. They should be reported in full for the period when they were incurred, regardless of whether acquired or developed in house, and should not be registered as an element of depreciation.

Capital expenditures include:

- land acquired for R&D use (e.g. testing grounds, sites for laboratories and pilot plants),
- buildings constructed or purchased for R&D use, including major improvements, modifications and repairs,
- machinery and equipment- acquired for use in the performance of R&D. This category includes machinery, technical equipment, means of transport, tools, instruments, movable properties and equipment,
- computer software used in the performance of R&D for more than one year. It includes long-term licences or the acquisition of separately identifiable computer software, including program descriptions and supporting materials for both systems and applications software. The production costs (e.g. labour and materials) of internally produced software should be reported. Software from external vendors may be obtained through the outright purchase of rights or licences to use. Software used or licensed for one year or less should be reported under current expenditures,
- other intellectual property products- purchased patents, long-term licences or other intangible assets used in R&D which are used for more than one year.

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przystaneknauka.us.edu.pl/artykul/nanomedycyna-w-terapiach-przeciwnowotworowych.

The value of capital expenditures covers both expenditures on fixed assets linked to R&D put into use during a reporting year as well as expenditures incurred on ongoing investments during this period (i.e. on future fixed assets linked to R&D).

Current expenditures – expenditures incurred during a reporting year only on nanotechnology R&D. They include labour costs and other current costs. Labour costs cover gross wages and salaries (personal, impersonal, honoraria, bonuses and paid profit for distribution); salary overheads chargeable to the employer, including social security payments as well as grants for PhD students carrying out nanotechnology R&D. In the case of services outsourced completely to external units, costs of consultants services are classifies as financing nanotechnology R&D performed outside a reporting unit. Current expenditures do not include depreciation of fixed assets and VAT.

Labour costs related to nanotechnology R&D - expenditures incurred by a unit during a reporting year. They cover gross wages and salaries (personal, impersonal, honoraria, bonuses and paid profit for distribution); salary overheads chargeable to the employer, including social security payments as well as grants for PhD students carrying out nanotechnology R&D. Labour costs exclude costs of work of persons providing intermediary services, not included in data on nanotechnology R&D personnel (e.g. security, administration or central library, IT department personnel) which in a part related to nanotechnology R&D are included in current costs.

Internal R&D personnel in nanotechnology– persons employed in a statistical unit who contribute to a unit's intramural R&D. It includes all persons engaged directly in R&D, regardless of whether they are employed by a statistical unit or are external contributors fully integrated into a statistical unit's R&D activities, as well as those providing direct services for the R&D activities (such as R&D managers, administrators, technicians and clerical staff).

Researchers – professionals conducting research and improving or developing concepts, theories, models, techniques, instrumentation, software or operational methods. Conducting R&D does not have to be based on formal qualifications or a job position. This category includes participants of doctoral studies conducing nanotechnology R&D. The tasks of researchers especially involve:

- conducting research, experiments, tests and analyses,
- developing concepts, theories, models, techniques, instrumentation, software and operational methods,
- gathering, processing, evaluating, analysing, and interpreting research data,
- evaluating the results of investigations and experiments, and making conclusions using different techniques and models,
- applying principles, techniques and processes to develop or improve practical applications,
- advising on designing, planning and organising the testing, construction,
- providing advice and support to governments, organisations and businesses on the application of research results,
- planning, directing and coordinating R&D conducted by institutions providing related services for other organisations,
- preparing scientific papers and reports.

Technicians and equivalent staff – persons participating in nanotechnology R&D, performing scientific and technical tasks related to the application of concepts and operational methods and using research equipment, normally under the supervision of researchers. Equivalent staff perform nanotechnology R&D tasks under the supervision of researchers. Their tasks include:

- carrying out bibliographic searches and selecting relevant material from archives and libraries,
- preparing computer programs,
- carrying out experiments, tests and analyses,
- providing technical assistance and support in R&D, or testing prototypes,
- · operating, maintaining and repairing research equipment,
- preparing materials and equipment for experiments, test and analyses,
- · recording measurements, making calculations and preparing charts and graphs,
- collecting information using accepted scientific methods,
- assisting in analysing data, keeping records and preparing reports,
- carrying out statistical surveys and interviews.

Other supporting staff – this category includes skilled and unskilled craftsmen, and administrative, secretarial and clerical staff participating in nanotechnology R&D or directly associated with such works. This group also covers persons dealing with personnel and financial aspects if their work is directly associated with nanotechnology R&D, including administrative and clerical works as well as providing materials and equipment necessary to carry out a nanotechnology R&D project or managing such materials and equipment. Personnel providing intermediary services, such as canteen, security or cleaning services, is excluded.

Full-time equivalent (FTE) – a conversion unit defined as the ratio of working hours actually spent on R&D during a reporting period (usually a calendar year) divided by the total number of hours conventionally worked in the same position by an individual or by a group. One full-time equivalent (FTE) means one person-year devoted exclusively to R&D.

The business enterprise sector - private and public entities as well as non-profit institutions serving enterprises whose primary activity is the production of goods or services for sale at economically significant prices.

The government sector – units of state and local government as well as non-market non-profit institutions controlled by government sector units that are not part of the higher education sector.

Examples: scientific institutes of the Polish Academy of Sciences, research units, hospitals and clinics not providing training if they are controlled and financed by the government sector units.

The higher education sector - includes all universities, colleges of technology and other institutions providing formal tertiary education programmes, whatever their source of finance or legal status. It also includes university hospitals and clinics – whole or in part conducting nanotechnology R&D as well as archives, libraries, museums, historical sites, botanical gardens administered by units of the higher education institutions or affiliated with them.

The private non-profit sector – so-called non-profit institutions. Private non-profit institutions include foundations (e.g. the Foundation for Polish Science), political parties, trade unions, consumers' associations, societies and associations (professional, scientific, religious and other) as well as natural persons and organisations dealing with promoting, financing and other forms of supporting scientific research.

Nanotechnology firm – a firm using nanotechnology in production of goods or services and/or conducting nanotechnology R&D.

## 7. Organisation and management of survey implementation

The author unit carrying out biotechnology and nanotechnology surveys is the Statistical Office in Szczecin. Employees of the Centre for Science, Technology, Innovation and Information Society Statistics, who are responsible for organisation of the survey implementation as well as compilation, analysis and presentation of results, make up a coordinating team.

Main tasks of coordinators include:

- preparing assumptions for selecting units for the surveys,
- preparing the survey schedules,
- verification of the survey files,
- preparing model questionnaires (datasets) for the surveys,
- preparing assumptions for logical and accounting control of the questionnaires (datasets),
- preparing mock-ups of result tables together with algorithms for their calculation,
- division of tasks related to the implementation of the surveys,
- supervision over the course of the surveys (i.a. on-going clarification of doubts reported by statisticians or reporting units),
- controlling correctness of datasets,
- analysing result tables,
- preparing and transferring data for publications and databases of Statistics Poland,
- preparing data for the OECD,
- on-going monitoring of issues related to biotechnology and nanotechnology,
- analysis of government and strategic documents.

Survey coordinators closely co-operate with a team of programmers from the Centre for Data Engineering in the Statistical Office in Szczecin. The Centre supports processing of data collected from respondents and contributes to their effective verification and analysis by providing, i.a. reports controlling correctness of data.

The tasks of the team from the Centre for Data Engineering include, i.a. developing IT system of the survey and creating new functionalities which can streamline everyday work of statisticians and coordinators. Additionally, the Centre is also responsible for operating an application PNT units facilitating comprehensive compilation of all information regarding a given reporting unit held by the Office.

Statisticians, who are employees of the Survey Implementation Department at the Statistical Office in Szczecin, are responsible for direct contact with respondents. Their tasks also include registering paper questionnaires in IT system of the survey as well as sending paper based correspondence, that is sending reminders about a reporting obligation.

Implementation of the surveys requires co-operation with other units of official statistics:

- the Statistical Office in Łódź responsible for preparing graphic layout of questionnaires (datasets);
- the Statistical Computing Centre responsible for developing a survey application on the Reporting Portal, supporting functionalities of the Reporting Portal (sending reminders to its users, e.g. about an imposed reporting obligation, impending date of fulfilling a reporting obligation).

The surveys are implemented in accordance with provisions of the Statistical survey program of official statistics and adhering to ethics of a statistician, especially the principle of maintaining statistical confidentiality and protecting collected data – pursuant to the Act of 29 June 1995 on Official Statistics (Journal of Laws of 2023, item 773).

### 8. Presentation of survey results

Results of biotechnology and nanotechnology surveys are presented in the first place in a news release 'Biotechnology and nanotechnology in Poland' published annually in November. Publication 'Science and technology' published annually in March of the year following completing the survey edition includes two separate chapters on biotechnology and nanotechnology.

All above mentioned forms of publishing results are available in an electronic version on the website of Statistics Poland (*https://stat.gov.pl/obszary-tematyczne/nauka-i-technika-spoleczenstwo-informacyjne/nauka-i-technika/*).

Additionally, results of a biotechnology survey are also presented in database Local Data Bank:

Local Data Bank (BDL) – data by areas, category: Science and technology. Information Society, group: biotechnology (<u>https://bdl.stat.gov.pl/BDL/start</u>)

Biotechnology and nanotechnology data are also presented on the OECD website:

Key biotechnology indicators - OECD

Key nanotechnology indicators - OECD

Biotechnology and nanotechnology data are also published in Statistical Yearbook of the Republic of Poland available in an electronic form on the website: <u>https://stat.gov.pl/obszary-tematyczne/roczniki-statystyczne/</u>.

# 9. Breakdowns of presented data

Data on biotechnology and nanotechnology are presented by the following breakdowns:

- territorial this breakdown classifies data by: macroregions (NUTS 1), regions (NUTS 2 applies only to biotechnology) and voivodships;
- sectors of performance this classification results from the methodology of the Frascati Manual 2015 and divides entities engaged in R&D into one of four sectors:
  - the business enterprise sector (BES),
  - the government sector (GOV),
  - the higher education sector (HES),
  - the private non-profit sector (PNP);
- size classes this breakdown is based on the number of persons employed in an entity and divides entities into the following classes:
  - up to 49 persons employed,
  - 50-249 persons employed,
  - over 249 persons employed.

### 10. Survey quality assessment

An aim of surveys is providing information concerning biotechnology and nanotechnology in Poland. The main recipients of data are government and local self-government institutions, researchers and university teachers, students, PhD students, media as well as the OECD.

Efforts are being made to provide results of the highest quality. Due to extensive logical and calculating assumptions, errors and discrepancies in data are avoided. Responses given on questionnaires (datasets) are thoroughly analysed. If questions or doubts related to correct filling in of questionnaires (datasets) arise, reporting units may reach out to a contact person for substantial issues who helps filling in questionnaires correctly and explains methodological issues. Contact details of employees responsible for contact with reporting entities are available on the Reporting Portal in questionnaires (datasets) and on the website of Statistics Poland <u>http://form.stat.gov.pl/formularze/kontakt.htm</u>

Surveys are implemented in accordance with the schedule and their results are published in accordance with an editorial title-plan. Completeness of surveys conducted in 2022 amounted to 98% and 88% for surveys MN-01 and MN-02, respectively, 90% and 86% for surveys PNT-05 and PNT-06, respectively. Survey files are created using a purposive sampling method. Over 200 units were included in the survey file MN-01 in 2022, while in MN-02 almost 1300 units. Completeness of surveys using questionnaires (datasets) MN-01 and MN-02 as well as PNT-05 and PNT-06 is primarily affected by refusal to fill-in a questionnaire and lack of contact with a unit (despite using such sources of contact as, for example contact information included in the Base of Statistical Units or on an entity's website, data from the National Court Register). In order to improve completeness and timeliness of surveys, automatic reminders are sent to entities from the Reporting Portal as well as e-mails reminding about a reporting obligation. Additionally, entities are reminded by telephone. In the case of lack of contact with an entity, correspondence is sent by post reminding about an unmet reporting obligation.

Due to specificity of the survey, survey files are supplemented with new entities during implementation of the survey, which may be seen in coverage errors. Web scraping will be introduced for the most accurate reflection of the survey population and taking into account elimination of coverage errors.

Burden on respondents taking part in surveys is also analysed each year. Two questions placed at the end of a questionnaire (dataset) are used for this purpose – a reporting entity estimates time dedicated to filling in a questionnaire as well as time dedicated to collecting information necessary to fill in a questionnaire.

In order to reduce respondent burden:

- 1. Automatic filling in of data in is used in an electronic questionnaire (dataset),
- 2. Introducing information boxes as graphic elements of the user interface which are presented after pointing the cursor on them and contain additional explanation for a given issue,
- 3. Filling in boxes with data from the previous year, e.g. intramural expenditures, sales of products.

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### Annexes

- Annex 1. MN-01 Questionnaire on biotechnology research and experimental development
- Annex 2. MN-02 Questionnaire on biotechnology in business enterprises
- Annex 3. PNT-05 Questionnaire on nanotechnology research and experimental development
- Annex 4. PNT-06 Questionnaire on nanotechnology in business enterprises
- Annex 5. Detailed list of variables MN-01
- Annex 6. Detailed list of variables MN-02
- Annex 7. Detailed list of variables PNT-05
- Annex 8. Detailed list of variables PNT-06