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NOTE BY THE SECRETARIAT

This document revises the OECD's statistical definition of biotechnology, which had last been reviewed in 2008, and proposes the adoption of a statistical definition of nanotechnology in the same format.

This document partially fulfils the requirements of the project on 'Statistics and Indicators of Bio- and Nanotechnology' of the Programme of Work and Budget (PWB) of the BNCT for Biennium 2015-2016 (see Figure 1 of [DSTI/STP(2014)39]).

This version of the document takes into account the comments received throughout the revision process from delegates of both the BNCT and the Working Party of National Experts on Science and Technology Indicators (NESTI), as well as additional external experts.

It incorporates changes requested subsequent to the Third Session of the BNCT in May 2016, the Forth Session of the BNCT in December 2016, the Fifth Session of the BNCT in May 2017, and the NESTI Meetings of 2016 and 2017.

ACKNOWLEDGEMENT

This “Revised Proposal of the Revision of the statistical Definitions of Biotechnology and Nanotechnology” was developed and revised with the friendly support of the NESTI secretariat; Brigitte van Beuzekom and Fernando Galindo-Rueda provided and solicited valuable comments and input. H  l  ne Dernis of the OECD gave input on the IPC classification schemes.

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BACKGROUND AND MOTIVATION

Agreement on a harmonised application of clear statistical definitions of technologies is pertinent to the delineation of technology fields both with regard to each other and within the context of wider economic developments.

Biotechnology and nanotechnology are both enabling technologies, which find applications and give rise to innovations in many industry sectors, contributing to determine wide ranges of economic and societal impact.

Both technologies have raised the attention of policy makers in a wide spectrum of areas, ranging from ethics and governance to economic impact. At the OECD, the work in biotechnology and nanotechnology is shared between the Environment Committee, which is concerned with aspects of biotechnology and nanotechnology in relation to human and environmental safety, biodiversity, ecosystems, resource efficiency and waste, and the CSTP, which focuses on biotechnology and nanotechnology with regard to their scientific, technological and economic impact, and their roles for policies in both the public and private sector. CSTP also has responsibility for statistics on biotechnology and nanotechnology.

This document represents a review of hitherto used statistical definitions of biotechnology and nanotechnology, and provides recommendations for the application of these definitions for statistical purposes. The document does not consider merits or appropriateness of these definitions for other purposes including, for example, regulatory oversight for protection of health or environment.

Biotechnology, as it is commonly understood in the public science and technology policy context and analysed in an economic context, is considered to have started in the 1970s with the first gene-splicing and –transfer experiments. Enabled by modern molecular biology, the field of biotechnology is closely linked to biological sciences and fundamentally reliant on the involvement of biological material and systems in a technical process or application for it to be called ‘biotechnology’.

Nanotechnology, by contrast, is delineated only in that the underlying nanotechnology-based processes and applications are based on phenomena occurring on the nanometre scale (i.e. 1 and 100 billionth of a metre), independent of the materials involved or the scientific disciplines applied. Given nanotechnology’s strong dependence on instrumentation that makes the nanometre-scale accessible to targeted scientific experiments and exploitation of phenomena, the discipline of modern nanotechnology is understood to have commenced around the start of the millennium, enabled by the invention of the scanning tunnelling microscope in 1981.

The statistical definitions proposed in this document are conceived for supporting the conduct of two main types of statistical activities. Firstly, the definitions help guide data collection efforts through statistical surveys implemented by statistical agencies by informing how topics are to be described in such surveys and supporting decisions on question items to be included. Definitions are used for example in the context of reporting R&D statistics using the Fields of Research and Development in the OECD Frascati Manual (OECD, 2015), or for the purposes of collecting and reporting data on the use of technology in firms, as contemplated in the “OECD Framework for Biotechnology Statistics” (OECD, 2005), which introduces the notion of biotechnology-active and biotechnology-dedicated firms, employment, etc. and also contains proposals on application areas for biotechnology. The statistical definitions proposed underpin the OECD collection of key biotechnology and nanotechnology indicators and can provide a basis for future data collection that allows linking between technology development, use and innovation and economic impact.

For statistical activities based on administrative data, definitions provide a general reference framework against which to compare existing administrative classifications and tagging schema. On the basis of the proposed recommendations for statistical definitions of biotechnology and nanotechnology, this document also provides an updated approach for compiling statistics generated from patent data using established classification and tagging schemes in this area.

The statistical definitions proposed in this document are indicative rather than exhaustive and are expected to change over time as biotechnology and nanotechnology activities evolve. The list-based statistical definitions do not imply a classification of mutually exclusive sub-domains of either biotechnology or nanotechnology. Furthermore, biotechnology and nanotechnology are closely intertwined and there can be cross-overs between these two technology domains. The proposed definitions can be applied both in data collection efforts where overlap is allowed in reporting as well as when a choice has to be made on the most relevant item within, for example, the 2-digit level OECD classification of Fields of R&D. Allowing overlaps could inflate estimates that result from adding biotechnology and nanotechnology together unless the amount of the overlaps was known and subtracted from the sum.

The proposed statistical definitions for biotechnology and nanotechnology are based on a review process that has been driven by three main objectives:

- the updating of the statistical definitions to take into account the latest advances in both the field of biotechnology and nanotechnology (e.g. the inclusion of marine biotechnology terms, the invention of new breeding techniques, such as the so-called CRISPR-Cas9 gene editing technique in the former, and the increasing R&D activity on graphene in the latter)
- the adaptation of the OECD technology definitions to changes that have been applied to technology classifications, categories and codes (cf.: the International Patent Classification (IPC) symbols identifying biotechnology patents has undergone annual reviews by topical IPC committees and changes since a list of IPC codes was agreed to delineate the field of biotechnology)
- the alignment of all elements of a technology definition with regard to updates and additions that have been applied to specific elements only (*i.e.* in 2005, the terms “bioinformatics” and “nanobiotechnology” were added to the list-based statistical definition of biotechnology, but the list of patent symbols assigned to identify biotechnology patents has not yet been adapted).

STATISTICAL DEFINITIONS AND CLASSIFICATIONS OF BIOTECHNOLOGY

Proposed OECD statistical definition of biotechnology

The scope of potential definitions of biotechnology may vary with regard to the deliberate exclusion or inclusion of naturally occurring examples of biotechnologies.

The proposed single and list-based statistical definitions of biotechnology are provided in Box 1.

The proposed single statistical definition of biotechnology is deliberately broad. It covers all modern biotechnology but also many traditional or borderline activities. For this reason, the single statistical definition whenever practical should be accompanied by the list-based statistical definition, which operationalises the definition for measurement purposes.

The proposed list-based statistical definition of biotechnology is based on OECD “Framework for Biotechnology Statistics” (2005) and on the codes of the International Patent Classification (IPC) (WIPO, 2015).

The list-based statistical definition of biotechnology terms functions as an interpretative guideline to the single statistical definition. The list is indicative rather than exhaustive and is expected to change over time as data collection and biotechnology activities evolve. The list-based statistical definition does not imply a classification comprising mutually exclusive sub-domains of biotechnology.

It is recommended that agencies collecting statistical data provide survey respondents with versions of both the single statistical definition of biotechnology and the list-based statistical definition that most closely capture their content and intent. It is beyond the scope of this document to make specific recommendations on what specific questions and procedures should be used as optimal solutions will depend on practical constraints, the choice of survey instrument and other contextual factors.

It is recommended that statistical agencies provide an “other (please specify)” category when using the list-based statistical definition categories as question items. This will allow respondents to report biotechnology techniques that fit the single, but not the list-based statistical definition and will thus assist in updating the list-based statistical definition.

Interested readers can consult information on the different biotechnology definitions used by countries in their surveys contributing to the OECD’s annual statistical publication of Key Biotechnology Indicators (KBIs).¹

1 OECD, “Key Biotechnology Indicators”, <http://oe.cd/kbi>.

Box 1. Proposed OECD single and list-based statistical definitions of biotechnology (2016 update)**The single statistical 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.

The list-based statistical definition of biotechnology: A detailed glossary of the following terms is available in ANNEX A1: Glossary of terms used in the OECD list-based statistical definition of biotechnology.

- **DNA/RNA:** Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology, **large-scale DNA synthesis, genome- and gene-editing, gene drive.**
- **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, signalling, 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, **marker assisted breeding technologies, metabolic engineering.**
- **Process biotechnology techniques:** Fermentation using bioreactors, **biorefining,** bioprocessing, bioleaching, biopulping, **biobleaching,** biodesulphurisation, bioremediation, **biosensing,** biofiltration and phytoremediation, **molecular aquaculture.**
- **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..

NOTE: 2016 additions to the statistical definition adopted in 2006 are highlighted in grey.

Biotechnology in patent classification schemes

Patents are organised and indexed using patent classification systems, such as the International Patent Classification (IPC) or national versions (WIPO, 2015). As a part of the examination process, examiners assign patent classification codes to the patent application under examination; such an assignment is usually considered to be a reliable indication of the technology field(s), to which an invention belongs (OECD, 2009).

There is no one section of the IPC system that cleanly equates to the field of biotechnology, so that the IPC symbols assigned to patent documents in the field of biotechnology may cut across different Sections, Classes, Subclasses and Groups. In 2003, patent experts developed a list of IPC symbols corresponding to biotechnology for the OECD; this list was formally adopted by OECD in 2006.

As a result of the changes to IPC symbols implemented by WIPO, an update of IPC symbols is required in order to ensure consistency in the way statistics on biotechnology are produced.

The changes that are most relevant to the statistical biotechnology definition concern the creation of new biotechnology-relevant groups and descriptive elements under:

- Subclass **C40B** (“**Combinatorial Chemistry; Libraries, e.g. Chemical Libraries, *in silico* Libraries**”): Groups on “Libraries [of] arrays, [and] mixtures” were introduced (*i.e.* Groups C40B 40/00 – C40B 40/18), including titles on “**Libraries containing RNA or DNA which encodes proteins, e.g. gene libraries**”. These Subclasses were introduced both for subject matters of “Organic or Organic Macromolecular Compounds” and their “Methods of preparation” (C07), and for subject matters of “Biochemistry; Mutation or Genetics Engineering” (C12).
- Groups of “Medicinal preparations containing inorganic active ingredients” (**A61K 33/00**) and “Medicinal preparations containing materials or reaction products thereof with undetermined constitution”(A61K 35/00); the latter was significantly amended by addition of descriptive details on “**Materials from mammals; Compositions comprising non-specified tissues or cells; Compositions comprising non-embryonic stem cells; Genetically modified cells [...]**”.

WIPO also **deleted the rarely assigned Subclass C12S** (Processes using enzymes or micro-organisms to liberate, separate or purify a pre-existing compound or composition) between Version 2010.01 and Version 2013.01.

Table 1 below provides the proposed list of IPC symbols corresponding to biotechnology patents, with newly incorporated symbols highlighted in grey.

The list in Table 1 is bound to be subject to updates in line with changes in the IPC and its use may be adapted to meet specific analytical needs.

Table 1. List of patent symbols identifying biotechnology patents (2016 update)

IPC Symbol	Title
A01H 1/00	Processes for modifying genotypes
A01H 4/00	Plant reproduction by tissue culture techniques
A01K 67/00	Rearing or breeding animals, not otherwise provided for; New breeds of animals
A61K 35/12 - 768	Materials from mammals; Compositions comprising non-specified tissues or cells; Compositions comprising non-embryonic stem cells; Genetically modified cells (uncharacterised stem cells; vaccines or medicinal preparations containing antigens or antibodies)
A61K 38/00	Medicinal preparations containing peptides (peptides containing beta-lactam rings; cyclic dipeptides not having in their molecule any other peptide link than those which form their ring, e.g. piperazine-2,5-diones; ergoline-based peptides; containing macromolecular compounds having statistically distributed amino acid units; medicinal preparations containing antigens or antibodies; medicinal preparations characterised by the non-active ingredients, e.g. peptides as drug carriers)
A61K 39/00	Medicinal preparations containing antigens or antibodies (materials for immunoassay)
A61K 48/00	Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases; Gene therapy
C02F 3/34	Biological treatment of water, waste water, or sewage: characterised by the micro-organisms used
C07G 11/00	Compounds of unknown constitution: antibiotics
C07G 13/00	Compounds of unknown constitution: vitamins

IPC Symbol	Title
C07G 15/00	Compounds of unknown constitution: hormones
C07K 4/00	Peptides having up to 20 amino acids in an undefined or only partially defined sequence; Derivatives thereof
C07K 14/00	Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof
C07K 16/00	Immunoglobulins, e.g. monoclonal or polyclonal antibodies.
C07K 17/00	Carrier-bound or immobilised peptides; Preparation thereof
C07K 19/00	Hybrid peptides (hybrid immunoglobulins composed solely of immunoglobulins)
C12M	APPARATUS FOR ENZYMOLOGY OR MICROBIOLOGY (installations for fermenting manure; preservation of living parts of humans or animals; brewing apparatus; fermentation apparatus for wine; apparatus for preparing vinegar)
C12N	MICRO-ORGANISMS OR ENZYMES; COMPOSITIONS THEREOF (biocides, pest repellants or attractants, or plant growth regulators containing micro-organisms, viruses, microbial fungi, enzymes, fermentates, or substances produced by, or extracted from, micro-organisms or animal material; medicinal preparations; fertilisers); PROPAGATING, PRESERVING, OR MAINTAINING MICRO-ORGANISMS; MUTATION OR GENETIC ENGINEERING; CULTURE MEDIA (microbiological testing media)
C12P	FERMENTATION OR ENZYME-USING PROCESSES TO SYNTHESISE A DESIRED CHEMICAL COMPOUND OR COMPOSITION OR TO SEPARATE OPTICAL ISOMERS FROM A RACEMIC MIXTURE
C12Q	MEASURING OR TESTING PROCESSES INVOLVING ENZYMES OR MICRO-ORGANISMS (immunoassay); COMPOSITIONS OR TEST PAPERS THEREFOR; PROCESSES OF PREPARING SUCH COMPOSITIONS; CONDITION-RESPONSIVE CONTROL IN MICROBIOLOGICAL OR ENZYMOLOGICAL PROCESSES
C40B 10/00	Directed molecular evolution of macromolecules, e.g. RNA, DNA or proteins
C40B 40/02	Libraries per se, e.g. arrays, mixtures: Libraries contained in or displayed by micro-organisms or vectors
C40B 40/06	Libraries per se, e.g. arrays, mixtures: Libraries containing nucleotides or polynucleotides, or derivatives thereof
C40B 40/08	Libraries per se, e.g. arrays, mixtures: Libraries containing peptides or polypeptides, or derivatives thereof
C40B 50/06	Methods of creating libraries, e.g. combinatorial synthesis: Biochemical methods, e.g. using enzymes or whole viable micro-organisms
G01N 27/327	Investigating or analysing materials by the use of electric, electro-chemical, or magnetic means: biochemical electrodes
G01N 33/50	Investigating or analysing materials by specific methods not covered by groups: Chemical analysis of biological material, e.g. blood, urine; Testing involving biospecific ligand binding methods; Immunological testing (measuring or testing processes other than immunological involving enzymes or micro-organisms, compositions or test papers therefor; processes of forming such compositions, condition responsive control in microbiological or enzymological processes
G01N 33/53*	Investigating or analysing materials by specific methods not covered by the preceding groups: immunoassay; biospecific binding assay; materials therefor
G01N 33/54*	Investigating or analysing materials by specific methods not covered by the preceding groups: double or second antibody: with steric inhibition or signal modification: with an insoluble carrier for immobilising immunochemicals: the carrier being organic: synthetic resin: as water suspendable particles: with antigen or antibody attached to the carrier via a bridging agent: Carbohydrates: with antigen or antibody entrapped within the carrier

IPC Symbol	Title
G01N 33/55*	Investigating or analysing materials by specific methods not covered by the preceding groups: the carrier being inorganic: Glass or silica: Metal or metal coated: the carrier being a biological cell or cell fragment: Red blood cell: Fixed or stabilised red blood cell: using kinetic measurement: using diffusion or migration of antigen or antibody: through a gel
G01N 33/57*	Investigating or analysing materials by specific methods not covered by the preceding groups: for venereal disease: for enzymes or isoenzymes: for cancer: for hepatitis: involving monoclonal antibodies: involving limulus lysate
G01N 33/68	Investigating or analysing materials by specific methods not covered by the preceding groups: involving proteins, peptides or amino acids
G01N 33/74	Investigating or analysing materials by specific methods not covered by the preceding groups: involving hormones
G01N 33/76	Investigating or analysing materials by specific methods not covered by the preceding groups: human chorionic gonadotropin
G01N 33/78	Investigating or analysing materials by specific methods not covered by the preceding groups: thyroid gland hormones
G01N 33/88	Investigating or analysing materials by specific methods not covered by the preceding groups: involving prostaglandins
G01N 33/92	Investigating or analysing materials by specific methods not covered by the preceding groups: involving lipids, e.g. cholesterol
G06F 19/10 – 24	Digital computing or data processing equipment or methods, specially adapted for specific applications (data processing systems or methods specially adapted for administrative, commercial, financial, managerial, supervisory or forecasting purposes): Bioinformatics, i.e. methods or systems for genetic or protein-related data processing in computational molecular biology (in silico methods of screening virtual chemical libraries; in silico or mathematical methods of creating virtual chemical libraries)
* Those IPC codes also include subgroups up to one digit (0 or 1 digit). For example, in addition to the code G01N 33/53, the codes G01N 33/531, G01N 33/532, etc. are included.	
New IPC symbols with regard to the 2006 list are highlighted in grey.	
Where the listed IPC symbols refer to Subgroups and lower levels, superior titles (i.e. Section, Class, Subclass and Group titles are given in regular while the relevant Subgroup (and lower) titles are given in bold).	
For more details on the 2006 IPC classification scheme, see http://web2.wipo.int/classifications/ipc/ipcpub/#refresh=page .	

The proposed classification of biotechnology applications

Applications of biotechnology are detailed in the “classifications for biotechnology applications” (see Table 2 below), which had first been introduced in the Biotechnology Framework (OECD, 2005).

The BNCT proposes the addition of a classification for “marine”, in order to reflect the explicit inclusion of “marine biotechnology” into the OECD statistical definition of biotechnology.

Table 2. Proposed classification for biotechnology applications (2016 update)

Broad	Intermediate	Detailed
Human Health	Large molecule therapeutics and monoclonal antibodies (MABs) produced using rDNA technology	-
	Other therapeutics, artificial substrates, diagnostics and drug delivery technologies, gene therapy, etc.	Other therapeutics, drug delivery technologies, etc.
		Substrates (artificial bone, skin etc.)
		Diagnostics, gene delivery
Veterinary health	As above, for veterinary uses	As above
Marine	Technology and application directed towards/regarding seafood and new food products based on marine resources, fish health and -welfare. Application of new knowledge from genomes of relevant farmed species and parasites. Cultivation and use of marine biomass and residual raw materials for various purposes.	Marine animals and plants (aquaculture), marine bioprospecting, genetic resources and infrastructure for marine science.
Agriculture	New varieties of genetically modified (GM) plants, animals, and micro-organisms for use in agriculture, and silviculture. Cultivation and use of biomass and residual raw materials for various purposes. Application of new knowledge from genomes of relevant farmed species and parasites.	GM plants, incl. fruit trees, flowers, horticultural crops, grains, etc.
		GM animals for agriculture
		GM tree varieties for forestry
		GM micro-organisms for agriculture (including bio pest control)
	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, incl. fruit trees, flowers, horticultural crops, grains, etc.
		Non-GM animals for agriculture
		Non-GM tree varieties for forestry
		Non-GM micro-organisms for agriculture (including bio pest control)
		Diagnostics
Food and beverages processing	Bioprocessing, functional foods/nutraceuticals ⁰	Using bioprocessing or improved crop varieties to improve food quality and characteristics
Natural resources	Applications for mining,	Mining: extraction using micro-organisms, etc.

Broad	Intermediate	Detailed
	petroleum/energy extraction, 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 & 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		-

a. Nutraceuticals. Although nutraceuticals have been included with 'Food and beverages processing' this could also be included with "Human Health" as they are foods that are altered to improve health benefits.

STATISTICAL DEFINITIONS AND CLASSIFICATIONS OF NANOTECHNOLOGY

Proposed OECD statistical definitions of nanotechnology

Since the coining of the term “nanotechnology” in the context of science, technology and innovation, a diverse range of nanotechnology definitions and descriptions has been proposed; these differ depending on their context and objective, ranging from the delineation of the scope of a technical committee, such as the working definition of the term ‘nanotechnologies’ agreed by the International Organization for Standardization (ISO) in 2005 upon the creation of its Technical Committee (ISO/TC 229 Nanotechnologies),² to technical specification and standardisation terminologies of nanotechnologies, such as those published by ISO/TC 229 in 2010 (ISO, 2010), and revised in 2015 (ISO, 2015),³ to regulatory definitions, such the definition of the term “nanomaterial”, passed in 2011 by the European Union (EU, 2011).

The scope of potential definitions of nanotechnology may vary with regard to the deliberate exclusion or inclusion of naturally occurring examples of nanotechnologies (*e.g.* nanomaterials).

The proposed single and list-based statistical definitions of nanotechnology are provided in Box 2.

The proposed single statistical definition of nanotechnology is based on an OECD proposal (2013) and the ISO scope description.

The single statistical definition whenever practical should be accompanied by the list-based statistical definition, which operationalises the definition for measurement purposes.

The list-based statistical definition of nanotechnology terms functions as an interpretative guideline to the single statistical definition. The list is indicative rather than exhaustive and is expected to change over time as data collection and nanotechnology activities evolve. The list-based statistical definition does not imply a classification comprising mutually exclusive sub-domains of nanotechnology.

It is recommended that agencies collecting statistical data provide survey respondents with suitably adapted versions of both the single statistical definition of nanotechnology and the list-based statistical definition.

It is recommended that statistical agencies provide an “other (please specify)” category when using the list-based statistical definition categories as question items. This will allow respondents to report

2 ISO/TC 229:
http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983 (accessed 12 December 2017).

3 Based on ISO (2015: “ISO/TS 80004-1:2015, Nanotechnologies — Vocabulary — Part 1: Core terms”: [...] “2.3. nanotechnology: application of scientific knowledge to manipulate and control matter predominantly in the nanoscale (2.1) to make use of size- and structure-dependent properties and phenomena distinct from those associated with individual atoms or molecules, or extrapolation from larger sizes of the same material (Note 1 to entry: Manipulation and control includes material synthesis)”.

nanotechnology techniques that fit the single but not the list-based statistical definition and will thus assist in updating the list-based statistical definition.

Interested readers can consult information on the different nanotechnology definitions used by countries in their surveys contributing to the OECD's annual statistical publication of Key Nanotechnology Indicators (KNIs).⁴

Box 2. Proposed OECD single and list-based statistical definitions of nanotechnology (2016)

The single statistical definition of nanotechnology:

The understanding of processes and phenomena and the application of science and technology to organisms, organic and inorganic materials, as well as parts, products and models thereof, at the nanometre-scale (but not exclusively below 100 nanometres) 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, and bulk matter for the production of knowledge, goods and services, like improved materials, devices, and systems that exploit these new properties.

The list-based statistical definition of nanotechnology:

- **Nanomaterial:** material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale.⁵
- **Nanoelectronics:** field of science and technology concerned with the development and production of functional electronic devices with nanoscale components.⁶
- **Nanophotonics:** branch of photonics concerned with interaction of photons with nanomaterials aiming to design optical or optoelectronic components.⁷
- **Nanomedicine:** medical application of nanotechnology (e.g. medical applications of nanomaterials and biological devices, to nanoelectronic biosensors, and even possible future applications of molecular nanotechnology such as biological machines).⁸
- **Nanomagnetics:** the study of the magnetic response of nanomaterials to an applied magnetic field, and their applications.
- **Nanomechanics:** a branch of nanoscience studying fundamental mechanical (elastic, thermal and kinetic) properties of physical systems at the nanometer scale.⁹

4 OECD, "Key Nanotechnology Indicators", <http://oe.cd/kni>.

5 Based on ISO (2015): "ISO/TS 80004-1:2015, Nanotechnologies — Vocabulary — Part 1: Core terms": [...] "2.4 nanomaterial: material with any external dimension in the nanoscale (2.1) or having internal structure or surface structure in the nanoscale (Note 1 to entry: This generic term is inclusive of nano-object (2.5) and nanostructured material (2.7))."

6 Based on ISO (2016): "ISO/TS 80004-12:2016, Nanotechnologies — Vocabulary — Part 12: Quantum phenomena in nanotechnology": [...] "6.2. nanoelectronics: field of science and technology concerned with the development and production of functional electronic devices with nanoscale components".

7 Based on ISO (2016): "ISO/TS 80004-12:2016, Nanotechnologies — Vocabulary — Part 12: Quantum phenomena in nanotechnology": [...] "6.3. nanophotonics: branch of photonics concerned with interaction of photons with nanomaterials aiming to design optical or optoelectronic components".

8 Based on: <https://en.wikipedia.org/wiki/Nanomedicine> (accessed 12 December 2017).

9 Based on: <https://en.wikipedia.org/wiki/Nanomechanics> (accessed 12 December 2017)

- **Nanofiltration:** a membrane filtration process used for the softening of water and the removal of organic matter; includes nano-membranes.¹⁰
- **Nanotools:** multi-component tools and devices used for manipulation, nanolithography and nanofabrication.
- **Nanoinstruments or –devices:** multi-component instruments or devices used for observation, analysis or control of matter at the nanometer scale.
- **Nanomanufacturing:** intentional synthesis, generation or control of nanomaterials, or fabrication steps in the nanoscale, for commercial purposes.¹¹
- **Nanobiotechnology:** application of nanoscience or nanotechnology to biology or biotechnology. This includes the application of nanotechnology to human health and veterinary science.¹²
- **Bionanotechnology:** application of biology to nanotechnology, i.e. the use of biological molecules in nanomaterials, nanoscale devices or nanoscale systems.¹³
- **Catalysis:** the study and application of catalytic process that are based on nanotechnology-enabled components.
- **Software for modelling and simulation:** the development and application of software for the modelling and simulation of nanoscale phenomena (i.e. phenomena occurring at a length scale between 1 nm and 100 nm).

The nanotechnology patent classification scheme

For the purposes of nanotechnology statistics based on patent data, the OECD uses the nanotechnology definition introduced by the European Patent Office (EPO):

The term nanotechnology covers entities with a controlled geometrical size of at least one functional component below 100nm in one or more dimensions susceptible to make physical, chemical or biological effects available which are intrinsic to that size. It covers equipment and methods for controlled analysis, manipulation, processing, fabrication or measurement with a precision below 100nm. (Scheu, 2006)

The EPO’s definition of nanotechnology underpins the patent tagging system Y01N, developed in 2003, and since then revised into a set of IPC Subclasses in 2011(EPO, 2013). The full list of IPC Codes uniquely assigned to nanotechnology patents is given in Table 3 below.

10 Based on: <https://en.wikipedia.org/wiki/Nanofiltration> (accessed December 2017)

11 Based on ISO 2015): “ISO/TS 80004-1:2015, Nanotechnologies — Vocabulary — Part 1: Core terms”: [...] “2.11. nanomanufacturing: intentional synthesis, generation or control of nanomaterials (2.4), or fabrication steps in the nanoscale (2.1), for commercial purposes”.

12 Based on ISO (2011): “ISO/TC 229 80004-5:2011, Nanotechnologies -- Vocabulary -- Part 5: Nano/bio interface”: [...] “3.1. nanobiotechnology: application of nanoscience (2.2) or nanotechnology (2.3) to biology or biotechnology (Note: This includes the application of nanotechnology to human health and veterinary science.)”..

13 Based on ISO (2011): “ISO/TC 229 80004-5:2011, Nanotechnologies -- Vocabulary -- Part 5: Nano/bio interface”: [...] “3.2. bionanotechnology: application of biology to nanotechnology (2.3), i.e. the use of biological molecules in nanomaterials (2.4), nanoscale (2.1) devices or nanoscale systems”.

Table 3. List of IPC patent codes uniquely assigned to nanotechnology patents

IPC Patent Code	Title
B82Y5	Nanobiotechnology or nano-medicine
B82Y10	Nanotechnology for information processing, storage and transmission
B82Y15	Nanotechnology for interacting, sensing and actuating
B82Y20	Nanotechnology for optics
B82Y25	Nanomagnetism
B82Y30	Nanotechnology for materials and surface science
B82Y35	Methods or apparatus for measurement or analysis of nanostructures
B82Y40	Manufacture or treatment of nanostructures

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ANNEX A1: GLOSSARY OF TERMS USED IN THE OECD LIST-BASED STATISTICAL DEFINITION OF BIOTECHNOLOGY

The detailed glossary of terms used in the OECD list-based statistical definition of biology was first introduced in the Biotechnology Framework (2005), and subsequently updated in 2008 (OECD, 2005). The glossary below aims to provide additional details on each one of the terms in the list-based statistical definition of biotechnology; the glossary is to be regarded as an indicative rather than an exhaustive guideline. The descriptions below were provided during by experts committees of the OECD, and further clarified by the relevant OECD secretariats.

Glossary of terms used in the OECD list-based statistical definition of biotechnology, 2016 update

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

- 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.
- Large-scale DNA synthesis: An automated creation of deoxyribonucleic acid (DNA) molecules.
- Genome- and gene-editing: A type of manipulation of the genome, in which DNA is inserted, deleted or replaced in the genome of a living organism using engineered nucleases, or "molecular scissors."
- Gene drive: A technique that promotes the inheritance of a particular gene to increase its prevalence in a population.

- 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.

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.

- 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.
- 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: Structures (typically proteins) found in the plasma membrane (surface) of cells that tightly bind specific molecules (organic molecules, proteins, viruses etc.). Some (relatively rare) receptors are located inside the cell (e.g. free-floating receptor for Retin-A). Both (membrane and internal) types of receptors are a functional part of information transmission (i.e. signalling) of the cell.

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

- 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 (an example is 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.

- Marker assister breeding technologies (AKA: marker aided selection (MAS)): A selection process used in

plant and animal breeding, where a trait of interest is selected based on a marker (morphological, biochemical or DNA/RNA variation) linked to a trait of interest (e.g. productivity, disease resistance, abiotic stress tolerance, and quality), rather than on the trait itself.

- **Metabolic engineering:** The practice of optimizing genetic and regulatory processes within cells to increase the cells' production of a certain substance.

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

- **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.
- **Bioleaching:** 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).
- **Biorefining:** A process, in which biomass is converted to produce fuels, power, heat, and value-added chemicals.
- **Biosensing:** A detection- or sensing-process based on a sensor, in which a biological component is combined with a physicochemical detector.
- **Molecular aquaculture:** A biotechnological discipline that is concerned with the structure and function of biological macromolecules essential to the cultivation (or farming) of fish, crustaceans, molluscs, aquatic plants, algae, and other aquatic organisms.

Gene and RNA vectors: Gene 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.
- Viral vectors: Certain (retro-) viruses that are used by genetic engineers to carry new genes into cells.

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. Secondly, it involves techniques such as the three-dimensional 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.

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

- Covers the interface between physics, biology, chemistry and the engineering sciences and which, among other things, 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.

NOTE: 2016 additions to the glossary adopted in 2006 are highlighted in grey.